[redacted]

No. 135

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1956

FLOYD E. KIDD,

Petitioner,

VS.

MERCK & COMPANY, INC.,

Respondent

APPENDIX TO BRIEF OF APPELLANT
IN COURT BELOW - 1a - 21a

APPENDIX TO BRIEF OF APPELLEE
IN COURT BELOW - 1b - 9b

No. 1025

No. 12918

MAY 1957
JOHN T. FEY, Clerk

United States Court of Appeals

For the Sixth Circuit

MERCK & COMPANY, INC.,

Appellant,

v.

FLOYD E. KIDD,

Appellee.

Appeal from the United States District Court for the Eastern District of Tennessee, Northern Division

---

APPENDIX TO BRIEF OF APPELLANT

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LIST OF RELEVANT DOCKET ENTRIES

Jan. 26, 1955 — Complaint filed.

Mar. 9, 1955 — Answer of defendant, filed. Copies served by Atty.

Nov. 14, 1955 — Order allowing substitution of complaint.

Nov. 14, 1955 — Amended complaint, filed.

Nov. 15, 1955 — Order of jury trial — all plaintiff's evidence heard and at close of same defendant moved for a directed verdict in its favor which was overruled; all defendant's evidence and at close of same defendant renewed its motion for a directed verdict which was overruled; thereupon jury heard argument of counsel, and respited to Nov. 16, 1955, at 9 A. M.

Nov. 16, 1955 — Order of Jury Trial continued — charge of the Court and verdict for plaintiff in amount of $12,000.00.

Nov. 18, 1955 — Final Judgment of $12,000.00 in favor of plaintiff and costs, execution awarded but issuance is stayed.

Nov. 22, 1955 — Defendant's motion for judgment notwithstanding verdict joined with its motion for a new trial, filed.

Jan. 12, 1956 — Transcript of testimony of defendant's motion for directed verdict, filed.

Jan. 12, 1956 — Transcript of Court's charge, Nov. 16, 1955, filed.

Feb. 17, 1956 — Motion for judgment or for a new trial heard by the Court and taken under advisement.

Mar. 19, 1956 — Order overruling defendant's motion for judgment N. O. V. and its motion for a new trial.

April 5, 1956 — Notice of Appeal, filed.

May 3, 1956 — Transcript of testimony of November 15 & 16, 1955, filed.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE, NORTHERN DIVISION

CIVIL ACTION NO. 2587

FLOYD E. KIDD,

Plaintiff,

v.

MERCK & COMPANY, INC.

Defendant.

COMPLAINT

(Filed January 26, 1955)

Comes the plaintiff, Floyd E. Kidd, and sues the defendant, Merck & Company, Inc., for damages in the sum of $50,000.00, and for his cause of action, says:

First Count

1. Plaintiff is a citizen and resident of the State of Tennessee, residing in Knox County, and the defendant is a foreign corporation organized and existing under the laws of the State of New Jersey. It is qualified to do and is doing business in the State of Tennessee, and its agent for the service of process in the State of Tennessee is The Corporation Company, Hamilton National Bank Building, Knoxville, Tennessee. The matter in controversy exceeds the sum of $3,000.00, exclusive of interest and costs. The jurisdiction of this Court depends upon the diversity of citizenship between the parties, and the amount in controversy.

2. The defendant, Merck & Company, Inc., among its many other activities, collects human blood from profes-

sional donors, processes it in various forms, places it on the market, and sells it for a profit through the various channels of the trade. Among its many customers throughout the world is the Sisters of Mercy of Nashville, Tennessee, Inc., doing business as St. Mary's Memorial Hospital, located in Knoxville, Tennessee. One of the defendant's products bears the trade name, "Lyovac Normal Human Plasma (Irradiated)", and the defendant processes, packages and sells the same in interstate commerce and within the State of Tennessee to be administered intravenously to injured persons as a substitute for whole blood, especially in cases of shock and hemorrhage, for the purpose of restoration and maintenance of body proteins, and for the purpose of reestablishing blood volume following hemorrhage.

3. The said plasma is supplied by the defendant manufacturer in a sealed package containing one bottle, with a vacuum-tight closure, of pooled original plasma in dry form which is restored to full volume prior to administration by adding an equal amount of diluent (citric acid solution) contained, in an accompanying bottle, both bottles being equipped with outer aluminum closures, and both being packaged together in the sealed package referred to which is so constructed that its contents reach the patient without possibility of alteration by intermediate parties. Not only is the said plasma so packaged as to eliminate any possibility of alteration, but the method of distribution and storage is such that no reasonable opportunity for substitution of or for tampering with the sealed package is afforded third parties in the interim between the defendant manufacturer's physical control of the plasma and its administration to the patient.

4. On or about March 8, 1954, the plaintiff was admitted as a patient to St. Mary's Memorial Hospital, suffering from the loss of blood due to a leg wound, and for the aforesaid

purposes was administered intravenously by agents and employees of said hospital "Lyovac Normal Human Plasma (Irradiated)", which had been processed, packaged and sold for the aforesaid purposes by the defendant to St. Mary's Memorial Hospital and in turn sold for those purposes by St. Mary's Memorial Hospital to the plaintiff.

5. The said plasma, which had been processed, packaged and distributed by the defendant as aforesaid contained a filthy, inherently dangerous and sometimes deadly substance known as serum hepatitis (SH) virus when it was sold by defendant to St. Mary's Memorial Hospital. The defendant failed to use due care and was negligent in one or more steps in the collection, processing or packaging of said plasma so as to cause or permit it to contain the said virus. The particulars of the defendant's negligence and failure to use due care are known to or are accessible to the defendant, and are unknown to and are inaccessible to the plaintiff.

6. The defendant was negligent, apart from its negligence in the collection, processing or packaging of said plasma, in that it placed the same on the market for the purposes aforesaid knowing that it might contain said filthy and inherently dangerous substance, and knowing that the plaintiff and others similarly situated probably would not know that it might contain said substance. The plaintiff in fact did not know that said plasma might contain said filthy and inherently dangerous substance prior to or at the time the plasma was administered to him and said plasma did in fact contain said substance.

7. About two months after being administered said plasma, and as the direct result thereof, the plaintiff developed a very serious liver disease known as yellow jaundice, transfusion jaundice or serum hepatitis. The disease was caused by the presence of the said SH virus in the said plasma. As a result thereof the plaintiff suffered much pain, nausea, and discomfort, was bedfast for a long period of,

time, and was required to incur substantial medical and hospital bills in an effort to be cured of the disease. He lost substantial sums of money by reason of his inability to work, and he charges that his capacity for work and labor and for the enjoyment of life has been permanently impaired. Many important functions of the liver have been greatly impaired and the liver reserve depleted. He is subject to recurrences of the disease in acute stages accompanied by further pain, anxiety, nausea, and monetary losses. The original disease, as well as relapses, often results in death. The plaintiff is faced with this ever present possibility throughout his uncertain future, and as a result thereof he suffers constant fear and apprehension.

Second Count

8. Plaintiff adopts herein by reference paragraphs 1, 2, 4 and 7 of the preceding first count, and further avers that said plasma, which had been processed, packaged and distributed by the defendant as aforesaid, contained a filthy, inherently dangerous and sometimes deadly substance known as serum hepatitis virus when it was sold by defendant to St. Mary's Memorial Hospital, and in turn sold by St. Mary's Memorial Hospital to the plaintiff.

9. In marketing said plasma as aforesaid the defendant impliedly warranted that it was of merchantable quality and that it was fit for the aforesaid purposes, when in fact it was not of merchantable quality and was unfit and dangerous to the life and health of the plaintiff. In marketing said plasma as aforesaid the defendant violated, among other sections, the following section of the Code of Tennessee:

> "7208. **Implied Warranties of Quality.** — Subject to the provisions of this article and of any statute in that behalf, there is no implied warranty or condition as to the quality or fitness for any particular purpose of

goods supplied under a contract to sell or a sale, except as follows:

"(1) Where the buyer, expressly or by implication, makes known to the seller the particular purpose for which the goods are required, and it appears that the buyer relies on the seller's skill or judgment (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be fit for such purposes.

"(2) Where the goods are bought by description from a seller who deals in goods of that description (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be of merchantable quality * * *."

Third Count

10. The plaintiff adopts herein by reference paragraphs 1, 2, 4, 7 and 8 of the preceding first and second counts, and further avers that the defendant was negligent in the premises, which negligence proximately resulted in the plaintiff's contraction of the said liver disease with the said losses and damages resulting to him, in that the defendant, in the marketing of said plasma which contained a filthy, inherently dangerous and sometimes deadly substance, to-wit: the virus of serum hepatitis, violated the following sections of the Supplement to the Code of Tennessee, the same being a part of the Tennessee Food, Drug and Cosmetic Act:

"6580.3 **Prohibited Acts.** — The following acts and the causing thereof within the State of Tennessee are prohibited:

"(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded * * *."

"6580.15 **Drugs or Devices Deemed Adulterated.** — A drug or device shall be deemed to be adulterated:

"(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *".

Fourth Count

11. The plaintiff adopts herein by reference paragraph 10 of the preceding Third Count; including all of the material therein adopted except the quoted sections from the Supplement to the Code of Tennessee, and in lieu of said sections charges that the defendant was guilty of proximate negligence in the manner stated and with the results stated in that it violated the following sections of Title 21, United States Code (being a part of the Federal Food, Drug, and Cosmetic Act:

"331. **Prohibited Acts**

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. * * *."

"351. **Adulterated Drugs and Devices**

A drug or device shall be deemed to be adulterated —

Poisonous, insanitary, etc., ingredients

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *."

Plaintiff therefore avers that a cause of action has accrued to him under each of the foregoing four counts of his complaint, and hence he sues the defendant for the aforesaid sum of $50,000.00, and demands a jury to try the cause.

FRANK H. MARSH, JR.,
Attorney for Plaintiff,
Hamilton National Bank Building,
Knoxville, Tennessee.

POORE, COX, BAKER & McAULEY,
301 Fidelity Bankers Trust Bldg.,
Knoxville, Tennessee.
Of Counsel

BOND

We acknowledge ourselves sureties for costs up to the sum of $250.00.

This January 25, 1955.

FRANK H. MARSH, JR.
BEN F. McAULEY.

ANSWER

(Filed March 9, 1955).

Comes the defendant Merck & Co., Inc., and for answer to the complaint filed against it in this cause, says:

1. The allegations of Paragraph 1 of the complaint with reference to the citizenship and residence of the respective parties are admitted, but it is denied that defendant is liable to plaintiff in any amount.

2. The allegations of Paragraph 2 of the complaint are admitted except as to those allegations undertaking to explain the purposes and use of the blood plasma, and as to these allegations, defendant would show that its plasma has various uses, the necessity and occasions for which use or uses will depend upon many circumstances.

3. The allegations of Paragraph 3 of the complaint are admitted except as to the allegation that said plasma is so packed, bottled and sealed as to eliminate any possibility of alteration between the time the plasma is packed and sealed and its administration to the patient. After the plasma leaves the possession and control of the manufacturer it is always subject to alterations and contamination if improperly handled or used while in the possession of others, and special attention and caution is called to this and other haz-

ards in the instructions accompanying the plasma, and for these reasons said allegations are denied.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the complaint and for this reason said allegations are denied.

5. and 6. Defendant denies the allegations contained in Paragraphs 5 and 6 of the complaint. The defendant would show that in the use of whole blood, blood plasma and other similar substances for transfusion purposes there is always the possibility of the presence of a virus capable of producing serum hepatitis and this fact is known and recognized by all of the doctors and leading medical authorities throughout the country. Despite careful processing of blood and blood plasma there is still the possibility that the finished plasma may contain the hepatitis virus since no method, non-injurious to the blood or blood plasma, is known which will in all cases destroy or inactivate the virus. Accordingly, the use of blood plasma involves a calculated risk that the patient may develop serum hepatitis. This calculated risk was well known to plaintiff's attending doctors and physicians and was assumed by them and by plaintiff. In the distribution of defendant's plasma these facts and this calculated risk are expressly called to the attention of all purchasers and users in the instructions and pamphlets which accompany each bottle of plasma and no warranties of any kind are ever made by the defendant in the distribution and sale of its blood plasma against the aforesaid possibilities.

7. Defendant alleges that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 of the complaint with reference to plaintiff's contracting or developing a serious liver disease known as yellow jaundice but it is specifically and emphatically denied that plaintiff contracted said seri-

ous disease from any plasma manufactured by your defendant. Defendant would further show that is without information or knowledge sufficient to form a belief as to the truth of all the other allegations contained in Paragraph 7 of the complaint and for this reason all of the remaining allegations are denied.

8. Defendant denies the allegations of Paragraph 8 of the complaint.

9. Defendant denies the allegations contained in Paragraph 9 of the complaint. Defendant would show that there were no warranties and that there was no privity of contract between the plaintiff and the defendant.

10. Defendant denies the allegations contained in Paragraph 10 of the complaint.

11. Defendant denies the allegations contained in Paragraph 11 of the complaint.

All other allegations of the complaint not herein denied, modified or explained, are here and now denied as fully and completely as if specifically denied.

And now having fully answered said complaint, defendant begs to be hence dismissed from all liability in the premises with its reasonable costs.

JOSEPH A. McAFEE,
Attorney for Defendant,
312 Park National Bank Bldg.,
Knoxville, Tennessee.

Of Counsel:
EGERTON, McAFEE, ARMISTEAD & DAVIS,
312 Park National Bank Building,
Knoxville, Tennessee.

I hereby certify that I have this day mailed a copy of the foregoing answer to Frank N. Marsh and Poore, Cox, Baker & McAuley, attorneys for plaintiff, this the 9th day of March, 1955.

JOSEPH A. McAFEE,
Attorney for Defendant.

ORDER ALLOWING SUBSTITUTION OF COMPLAINT

(Filed November 14, 1955)

Upon application of the plaintiff and by agreement of the parties it is ordered that the complaint heretofore filed in this cause be withdrawn and that the plaintiff may substitute in lieu thereof his Amended Complaint.

It is further ordered that the Answer of the defendant heretofore filed to the complaint will stand filed as an answer to the Amended Complaint.

ENTER: Robert L. Taylor, Judge.

O.K.:
Frank H. Marsh, Jr.
Attorney for Plaintiff.
Joseph A. McAfee,
Attorney for Defendant.

AMENDED COMPLAINT

(Filed November 14, 1955)

Comes the plaintiff, Floyd E. Kidd, and sues the defendant, Merck & Company, Inc., for damages in the sum of $50,000.00, and for his cause of action, says:

Amended Complaint

1. Plaintiff is a citizen and resident of the State of Tennessee, residing in Knox County, and the defendant is a foreign corporation organized and existing under the laws of the State of New Jersey. It is qualified to do and is doing business in the State of Tennessee, and its agent for the service of process in the State of Tennessee is the Corporation Company, Hamilton National Bank Building, Knoxville, Tennessee. The matter in controversy exceeds the sum of $3,000.00, exclusive of interest and costs. The jurisdiction of this Court depends upon the diversity of citizenship between the parties, and the amount in controversy.

2. The defendant, Merck & Company, Inc., through one of its divisions known as Sharp & Dohme, among its many other activities, collects human blood from professional donors, processes it in various forms, places it on the market and sells it for a profit through the various channels of the trade. Among its many customers throughout the world is the Sisters of Mercy of Nashville, Tennessee, Inc., doing business as St. Mary's Memorial Hospital, located in Knoxville, Tennessee. One of the defendant's products bears the trade name "'Lyovac' Normal Human Plasma (Irradiated)", and the defendant processes, packages and sells the same in interstate commerce and within the State of Tennessee to be administered intravenously to injured persons as a substitute for whole blood, especially in cases of shock and hemorrhage, for the purpose of restoration and maintenance of body proteins, and for the purpose of re-establishing blood volume following hemorrhage.

3. The said plasma is supplied by the defendant manufacturer in a sealed package containing one bottle, with a vacuum-tight closure, of pooled original plasma in dry form which is restored to full volume prior to administration by adding an equal amount of diluent (citric acid solution) contained in an accompanying bottle, both bottles being equip-

ped with outer aluminum closures, and both being packaged together in the sealed package referred to.

4. On or about March 8, 1954, the plaintiff was admitted as a patient to St. Mary's Memorial Hospital, suffering from the loss of blood due to a leg wound, and for the aforesaid purposes was administered intravenously by agents and employees of said hospital "Lyovac Normal Human Plasma (Irradiated)", which had been processed, packaged and sold for the aforesaid purposes by the defendant to St. Mary's Memorial Hospital and in turn sold for those purposes by St. Mary's Memorial Hospital to the plaintiff.

5. The said plasma thus manufactured and distributed by the defendant contained a filthy, inherently dangerous and sometimes deadly substance known as serum hepatitis (SH) virus at the time it was placed upon the market by the defendant and thus administered to the plaintiff.

6. About two months after being administered said plasma, and as the direct result thereof, the plaintiff developed a very serious liver disease known as yellow jaundice, transfusion jaundice or serum hepatitis. The disease was caused by the presence of the said SH virus in the said plasma. As a result thereof the plaintiff suffered much pain, nausea, and discomfort, was bedfast for a long period of time, and was required to incur substantial medical and hospital bills in an effort to be cured of the disease. He lost substantial sums of money by reason of his inability to work, and he charges that his capacity for work and labor and for the enjoyment of life has been permanently impaired. Many important functions of the liver have been greatly impaired and the liver reserve depleted. He is subject to recurrences of the disease in acute stages accompanied by further pain, anxiety, nausea, and monetary losses. The original disease, as well as relapses, often results in death. The plaintiff is faced with this ever present possibility

throughout his uncertain future, and as a result thereof he suffers constant fear and apprehension.

7. In marketing said plasma as aforesaid the defendant was guilty of negligence which proximately resulted in the plaintiff's contraction of said liver disease with the said losses and damages resulting to him, and in marketing said plasma the defendant violated the following sections of the Supplement to the Code of Tennessee, the same being a part of the Tennessee Food, Drug and Cosmetic Act:

"6580.3. **Prohibited Acts.** — The following acts and the causing thereof within the State of Tennessee are prohibited:

"(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded. * * *

"6580.5 **Violations made misdemeanor.** —

(a) Any person who violates any of the provisions of section 6580.3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than thirty (30) days or a fine of not more than fifty ($50.00) dollars, or both such imprisonment and fine; * * *

"6580.15. **Drugs or Devices Deemed Adulterated.** — A drug or device shall be deemed to be adulterated:

"(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *"

Plaintiff therefore avers that a cause of action has accrued to him, and hence he sues the defendant for the aforesaid sum of $50,000.00, and demands a jury to try the cause.

FRANK H. MARSH, JR.,
Attorney for Plaintiff,
Hamilton National Bank Bldg.,
Knoxville, Tennessee.

POORE, COX, BAKER & McAULEY,
301 Fidelity Bankers Trust Bldg.,
Knoxville, Tennessee,
Of Counsel.

TRANSCRIPT OF TESTIMONY

(1) APPEARANCES:

For the Plaintiff:

POORE, COX, BAKER & McAULEY

Ben E. McAuley, Esq.

FRANK H. MARSH, JR., Esq.

For the Defendant:

EGERTON, McAFEE, ARMISTEAD & DAVIS

Joseph A. McAfee, Esq.

HAYWARD H. COBURN,

Philadelphia, Pennsylvania.

* * *

This cause came on to be heard before the Honorable Robert L. Taylor, Judge, of the United States District Court for the Eastern Distict of Tennessee, Northern Division, at Knoxville, Tennessee, and a jury, on November 15, 1955, and succeeding days, when the following proceedings were had, to-wit:

THE CLERK: Floyd E. Kidd, plaintiff, versus Merck & Company, defendant.

THE COURT: Are the parties ready?

MR. McAULEY: We have one witness under subpoena who is not here, but I assume he will be here.

MR. McAFEE: The defendant is ready, your Honor.

(2) If your Honor please, you have heard of Philadelphia lawyers, what fine lawyers they are. This is my first opportunity of having a fine Philadelphia lawyer with me. I have Mr. Hayward H. Coburn here who would like to participate in this case.

THE COURT: We are glad to have him.

MR. McAFEE: One other thing, your Honor. We have Mr. Barclay, who is the director of the biological production of Merck & Company, Sharp-Dohme Division, which we desire to remain in the courtroom as a representative of the defendant.

MR. McAULEY: No objection, your Honor.

THE COURT: All right. Call the jury.

(Whereupon, the jury was qualified, selected and impaneled.)

(Whereupon, the witnesses were sworn and the rule having been requested were excused from the courtroom.)

THE COURT: All right. Now, Mr. McAuley, you may make your explanatory statement on behalf of the plaintiff.

MR. McAULEY: Very well, your Honor. Ladies and gentlemen of the jury, I believe we have for the most part already acquainted you with the nature of this action, but a little more detail might be helpful.

(3) Mr. Kidd on March 8, 1954 — he, incidentally, is a building and painting contractor and he was working on a house he was building for sale. He had an electric power saw there and it jumped, bucked, or did something, but it cut his right leg across the top His wife was across the street and his son was on the job with him, and so they carried him in the automobile to the St. Mary's Hospital where he walked into the hospital and was there admitted and while there in the receiving ward was given certain injections, tetanus and various other shots that they give you in a hospital, including an injection or transfusion of this blood plasma.

Now, it might be in order to say that blood plasma is distinguished from whole blood. We all know what transfusions are and we have heard of plasma but we may confuse the two. I know I did until I got interested in this case.

Blood plasma is prepared by collecting into a pool from a number of donors — I believe Merck & Company used 125 donors. That blood is all put together in one pool and is processed and reduced to powder form and is irradiated with ultraviolet light and put into a bottle with a sealed aluminum inclosure in a powder form, and accompanied by

another bottle of solution, and these two bottles in the package are placed on the market.

When it is ready for use the bottle containing (4) the diluent is put on top of the bottle containing the plasma by way of a needle and it is mixed together and shaken up and a plastic tube connected with the end of the restored plasma hung on a rack, and ordinarily a needle inserted in the other end of this tube and inserted in the patient's arm and it drips into the patient's veins.

In this particular case that transpired. Doctor Gunn, and he is now in Louisville, Kentucky, at the veterans facility, and we have his deposition here. He testified that that process was carried out and that it was the Sharp & Dohme's plasma, or the Sharp & Dohme Division of Merck & Company, and that this plasma was administered as I have indicated.

Now, there are two kinds of hepatitis. One is infectious hepatitis which can be contracted by contaminated food, or the hands of people, or from water, and that sort of thing.

The other is serum hepatitis which can come only from blood or blood plasma or products of human blood introduced into the blood stream of the victim.

Now, there is a difference in the incubation period of the two types of hepatitis. Infectious hepatitis has a shorter incubation period. I believe from 12 to 28 days, something like that. The serum hepatitis, the kind that Mr. Kidd suffers from has an incubation period of a (5) longer period of time. Sixty to perhaps as much as 120 days and even longer in some cases.

Now, Mr. Kidd received this plasma on March 8, 1954, and in May he got along very well, even went home and was up and about and felt strong following the leg injury, and in May, on May 25, he was readmitted to the hospital with this liver ailment. He had been suffering from that condition for some two weeks before he was admitted.

So, he came down with it a little over 60 days after being given the plasma, and that is the criteria, that is the way the medical profession determines whether it is infectious hepatitis or serum hepatitis, and Doctor Acker's deposition is here and he so diagnosed this particular case.

Mr. Kidd's liver became swollen and it was distended. He was nauseated and he was tired and sluggish and in quite severe pain. He was treated at the hospital for about five days and then sent home, and that was in May, if you remember. And it was some time in, I believe, September, he was then in bed for about three months and he worried along with it until some time in April of this year, 1955, when he began to resume a little activity in his building and painting work.

And then in August he had a flare-up and his liver (6) became sore and tender again, and not since he contracted that disease has he been able to climb ladders or carry on the other usual activities that would be associated with the building and painting trade.

He has suffered losses by way of lost time; he has incurred certain medical bills, and he says he will continue to suffer these things and will continue to have these losses for the rest of his life, his condition being more or less chronic and subject to flaring up from time to time the rest of his life, and it is for those things that he brought this suit against the manufacturer of the plasma charging a violation of the Tennessee Act in that that plasma contained that virus which is within the meaning of the Act filthy and therefore adulterated.

THE COURT: Mr. McAuley, is it the contention of the plaintiff that the manufacturer violated the Act because this blood plasma was allegedly filthy?

MR. McAULEY: We say, your Honor, that it contained a virus and that in and of itself is the violation of the

Act, in the plasma not being free of the virus is therefore, and to that extent adulterated.

THE COURT: Does the plaintiff claim that his case comes within the meaning of the words "decomposed" or "putrid"? He does not rely on those words?

MR. McAULEY: He relies on the word "filthy" as a (7) violation of the Act.

THE COURT: Relies alone on the word "filth" as a violation of the Act.

MR. McAULEY: Yes, sir. Not the words "putrid" or "decomposed."

THE COURT: All right.

MR. McAULEY: Actually, I believe the word is "filthy."

THE COURT: Filthy.

MR. McAULEY: Yes, sir.

THE COURT: That is the definition of adulteration. You say an adulteration came about by reason of filth?

MR. McAULEY: Yes, sir the presence of this particular virus. Now, we say if it was one of the other healthy viruses it would not be filthy, but when you have a human host carrying it it would be a filthy substance.

THE COURT: All right. Mr. McAfee or Mr. Coburn, will you make an explanatory statement for the defendant.

MR. McAFEE: If the Court please, and ladies and gentlemen of the jury, in these modern times we are making great progress in medicine. Probably one of the greatest, useful and beneficial medicines that has come on the market recently is blood plasma.

It is used for the purpose of relieving shock and to replenish the blood in your body. It came into great use (8) during this past war when thousands of literally upon thousands of transfusions were given soldier boys on the battle-field where they had lost a tremendous amount of blood, suffering from shock.

Now they couldn't have given a whole blood transfusion there because in the giving of whole blood, and I am pointing this out to show a distinction between whole blood transfusion and blood plasma — now in giving whole blood transfusions you have got to match each person's blood with the blood of a donor, that is, match the blood of the donor to the blood of the patient you are giving it to, and it takes time and it takes tests to do this.

Now the advantage of blood plasma is that you don't have to go through with that. You can carry it with you right on the spot and give it to the patient.

It has great use in the practice of medicine for alleviating suffering and pain and saving lives today. But we admit, notwithstanding all of its great usefulness and benefits, it may carry with it a risk and that is a risk that a person might contract a hepatitis virus from it.

Now here is a point, and here is the reason why there is no negligence involved here in this case. There is absolutely no way — listen to this now — there is no scientific method or way that you can determine whether or not blood contains this virus. It cannot be seen, it cannot (9) be detected and it cannot be isolated — there is no method.

There is one other thing that this jury must remember as this proof develops, not only that it cannot be seen, it cannot be detected and cannot be isolated, but there is absolutely no way that you can destroy the virus in the plasma without destroying the plasma itself.

Here is another thing, ladies and gentlemen of the jury, blood plasma is not sold to the public like aspirin tablets and those medicines. Blood plasma, under the Federal law, can only be sold and given under a doctor's prescription, and the purpose of that is the doctor, himself, in each and every case must weight the risk when he gives plasma as to whether or not the risk justifies the giving of the plasma depending upon the seriousness of the patient's injuries.

Now, there are two kind of viruses — I mean hepatitis. There is what is called an infectious hepatitis which you can get from eating unsanitary food, water, taken through the mouth.

Then, there is serum hepatitis. There are a number of ways which you can contract this infectious hepatitis and serum hepatitis. There are various and sundry ways that you can get that from blood plasma. You can get it in other ways — you can get it from the use of an unsanitary needle that is injected into your arm where that needle has been injected into another person who had the (10) virus in his blood.

People who have been tattooed can obtain and contract this virus. Dope addicts who continually go into their arm with needles can likewise contract serum hepatitis — not infectious but serum hepatitis. And there are many other causes which produce it as we will prove during the course of this case.

And we say that there will be no proof here or not sufficient proof that will positively, that will positively show that this transfusion of this plasma was the cause of the plaintiff's trouble.

Now here is another thing. There is absolutely no difference between the virus that you get in infectious hepatitis than the virus that you get from serum hepatitis. It can't be told, there is no difference.

We say that it is not a filthy substance within the meaning of the Tennessee Pure Food & Drug Act, and, ladies and gentlemen, it has got to be a filthy substance within the meaning of that Act, otherwise the plaintiff cannot prevail in this lawsuit.

The Tennessee Pure Food & Drug Act provides this, ladies and gentlemen:

"The term 'contaminated with filth' applies to any food, drug, device or cosmetic not securely protected from dust, dirt and, as far as possible" — remember those (11) words — "and, as far as possible from all foreign or injurious substances."

We say that even though it could be possible for this plaintiff to have contracted hepatitis from this plasma, still it is not a filthy substance within the meaning of that Act because we took every precaution to protect it from it.

The truth about the matter is, that there is no way under the sun that you could keep it out.

And we say, ladies and gentlemen of the jury, that all of those will be our defenses in this case.

MR. McAULEY: May I make one explanatory statement as to the statute?

MR. McAFEE: Wait just a minute, I did want to add this — all right, that will be all.

MR. McAULEY: You were reading the definition of contaminated with filth. That is not a part of this lawsuit. The charge in the complaint: "6580.3. Prohibited Acts. — The following acts and causing thereof within the State of Tennessee are prohibited:

"(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded."

We have covered what adulteration means.

"6580.15. Drugs or Devices Deemed Adulterated:

(12) "(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *"

That is what we rest our case on.

The next part of this statute, which we are not concerned with is: "If it had been produced, prepared, packed or held under unsanitary conditions whereby it might be contaminated with filth."

We are not after that part, but over here is the term "contaminated with filth."

THE COURT: Then, if I understand you, Mr. McAuley, plaintiff agrees that this plasma was manufactured under sanitary conditions?

MR. McAULEY: We do, your Honor.

THE COURT: All right. Call your first witness.

Floyd E. Kidd,

called as a witness by and on his own behalf, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q You are Mr. Floyd E. Kidd?

A Yes, sir.

Q Where do you live, Mr. Kidd?

A 3814 Powers Street.

Q What street?

A Powers Street.

(13) Q How old are you, sir?

A Forty.

Q What is your occupation?

A I am a carpenter and painter.

Q How long have you followed that trade?

A Fourteen years.

Q Fourteen years?

A Yes, sir.

Q Mr. Kidd, on March 8, 1954, what were you doing?

A I was building a house on Carson Avenue.

Q Here in Knoxville?

A Yes, sir.

Q Was that – whose house was it?

A It was for myself.

Q Building and selling proposition?

A Yes, sir. I was building to sell.

Q State whether or not you sustained an accidental injury on that job.

A Yes, sir. I cut my leg with a power saw.

Q With a power saw?

A Yes.

Q What time of day was that, if you remember?

A It was around 2 o'clock.

Q In the afternoon?

A Yes, sir.

(14) Q And, now, following that accident, what did you do, where did you go?

A Well, I went to St. Mary's Hospital.

Q How did you get there?

A My wife and son took me in the automobile.

Q State whether or not your leg was bandaged in any way before you left the building site.

A My son had a shirt sleeve there and he tied that around my leg above the wound over my pants leg before I entered the receiving ward.

Q How did you get to the receiving ward from the hospital?

A Well, I walked to the door. Of course, my son and wife were holding me by the arm.

Q They were along with you?

A Yes, sir, and then they rolled – that little chair out there and I sat down in it and they pushed me on in the emergency room.

Q Were you conscious?

A Yes, sir, at all times.

Q While there in the receiving room of emergency room, will you describe what care was given you?

A Well, they gave me some shots, maybe three or four, and then they, of course, cleaned the wound and later they started the plasma.

(15) Q. Who started the plasma, if you remember?

A. Well, there was Doctor Gunn and, of course, there was another intern there. I didn't remember his name, or the nurse either one. But there were some more in there but later I got acquainted with Doctor Gunn and I knew he was the one that started the plasma.

Q Where was the plasma started, there in the receiving ward or upstairs?

A In the receiving ward.

Q How long did you stay in the receiving ward?

A Well, I guess I stayed down there an hour, something like an hour and a quarter.

Q Where did you go from the receiving ward?

A Went to the third floor to a room.

Q A regular hospital room?

A Yes, sir.

Q How long were you there?

A Well, they kept me there until around – well, it was dark. Maybe 6 or 6:30 in the afternoon; and they took me from there to the operating room, which I remember everything up until I entered the operating room.

Q That was about dark?

A Yes, sir.

Q Were you given any anesthesia or put to sleep or did you just lose consciousness?

(16) A. They gave me a shot down in the room before they took me to the operating room, and, of course, I was getting dizzy all the time on the way up but, before they entered the operating room why they put something

over my mouth, or face rather, and that was about the last thing I remember until I woke up in about three hours later.

Q Back in your room?

A Back in the room; yes, sir.

Q How long did you stay in the hospital, Mr. Kidd?

A I stayed nine days.

Q After you were discharged, where did you go?

A I went home.

Q That would put your home about what time, what date?

A Well, I left there—

Q About March 17 or 18?

A Yes, sir, I think that is about right.

Q Describe your progress. That is, from the leg injury, how did it get along?

A Well, my leg did well. It healed and I got to feeling good, pretty good. And after May 1st, around the middle of May, I would say, I got to getting sick. I just got so sick—

Q Did you go back to work any after you got out of the hospital the first time and before you went in the hospital a second time, did you do any work?

(17) A Yes, sir, a little bit; very little.

Q And what kind of work was it that you did?

A Well, it was just light work. Looking after what work I had started, you know.

Q You had some men working for you?

A Yes, sir. I had two boys working for me. I looked about that work.

Q You say, in May you began feeling bad again?

A Yes, sir. I got sick. In fact, I laid around two weeks and I just got so sick I couldn't walk and I couldn't eat, and I got in an awful shape. So my wife noticed me turn-

ing, you know, yellow — my wife noticed me turning yellow around my eyeballs.

Q And where else?

A The pupils, rather, and my urine started turning dark.

Q When did you first go to a doctor for that treatment? You say you had been in that shape for about two weeks and you went to a doctor?

A Yes, sir.

Q Who was that?

A Doctor Shoemaker. I went to Doctor Shoemaker two weeks later after I got to feeling bad, and he put me in St. Mary's Hospital and wanted to run these tests.

He said he thought he knew what was wrong with me, (18) so he put me over there and kept me five days. And Doctor Acker, which has been attending me, came in on the case and they told me what had happened, and he came in on Sunday morning, Doctor Acker did, and told me that—

Q Could you give us the date, what date did you enter the hospital?

A 25th day of May.

Q May 25?

A Yes.

Q Do you know what day of the week that was?

A I think it was on Thursday.

Q How soon after you entered the hospital—

THE COURT: Is that 1954?

MR. McAULEY: Yes, sir.

THE WITNESS: 1954.

By Mr. McAuley:

Q How soon after you entered the hospital were you seen by Doctor Acker?

A Well, he came that night.

Q The night of the 25th?

A Yes, sir.

Q All right. And I believe you stated you were in the hospital for five days under the care principally of Doctor Acker?

A Doctor Acker.

(19) Q Mr. Kidd, will you please describe, if you can, sir, to the jury whether or not you suffered any pain during the two weeks before the hospitalization, during the hospitalization and following the hospitalization?

A Yes, sir, I suffered awful. I seemed to hurt in my side. I swelled up.

Q Which side was it?

A My right side. It swelled up and I had a severe pain there at all times, and I was nauseated at all times, practically all the time, and I had a rash, too, and I walked the floor.

Q How did that rash affect you?

A Well, I just itched all over and I had to scratch. In other words, if you ever had poison ivy, it was something similar to that, I would say, and I walked the floor three nights — wait a minute, I mean three weeks, practically with that, up and down, through the night.

Q How about your appetite, were you able to eat regularly?

A I had to force down what I ate. Of course, the doctor told me to eat a high protein diet and I was so sick that I just couldn't eat. In fact, what I did eat I just forced down me.

Q What had been the state of your health prior to this May episode of 1954, had you been in good health or (20) poor health?

A Yes, sir, I was in good health.

Q Had you had any similar experience before?

A No, sir. I never had anything like that to happen to me before.

Q Mr. Kidd, I will ask you to state whether or not there was any particular odor about your body?

A Well, yes, sir. Everybody come to see me complained about me having this odor. I could tell it a little bit but naturally other people could tell it more than I could. My wife complained about it all the time.

Q Even your best friends wouldn't tell you to your face?

A No. They'd tell her and then, you know, later she would tell me about it, and it was pretty bad.

Q All right. Now, tell us, Mr. Kidd, how long you stayed at home following your return home from the hospital before you got out and began doing anything?

A I came home from the hospital — well, I stayed in bed for three months, full three months. The fourth month I got up and just went to stirring a little bit.

Q Just went to stirring a little bit?

A Yes, sir. Just in the bed and out.

Q That would be September?

A That's right, in September. So in November (21) Doctor Acker told me I could start doing a little light work, just maybe very light work, so I started stirring around and doing a little work around the house. I couldn't hold out long, maybe a couple of hours. I would just have to get up and go back to bed.

So I continued that way up until April of 1955.

Q What happened in April of 1955?

A I resumed my full work duties. Made it pretty well up until August.

Q Then what happened?

A Well, I had a relapse. I got to getting sick, vomiting and I got sore in my liver. And I went back to Doctor Acker and he run those liver tests on me again and he said that I had had a relapse and that the test was off track, a way off track, the last time to what they were the time before I went, which was about a month before that.

Q Do you have a tatoo mark on your arm?

A Yes, sir.

Q Which one is that?

A Right here (indicating to the left arm) Can't hardly see it, it is faded out.

Q What does it say?

A Its got my initials in it.

Q When did you get that tatoo?

A In 1929.

(22) Q About 25 years ago?

A Yes, sir. Just a kid.

Q Within 60 to 120 days after that tatoo, did you have any hepatitis trouble?

A No, sir. I never had anything like this before in my life.

Q Do you know, Mr. Kidd, whether or not your wife some time during your first day at the hospital admitted you in, that is, signed a paper and gave your name and that sort of thing?

A Well, I did not know – if she did it why I didn't know anything about it.

Q You have since learned that she did?

A Yes, sir.

Q At the time you did not know it?

A No, sir, I didn't know it at the time. Of course, after–

Q Mr. Kidd, could you tell us whether or not you

have incurred any medical bills as a result of the liver ailment?

A Sir?

Q. Did you have to pay out any money as a result of the liver ailment?

A Yes, sir.

Q Could you tell us what that amounted to?

(23) A Well, my hospital and doctors bills—

Q Do you have a list there?

A I think so. Do you want me—

Q Who was the first doctor that you saw?

A Doctor Shoemaker.

Q Doctor Shoemaker?

A Yes, sir. Doctor Kenneth Shoemaker.

Q He is the one who admitted you to the hospital?

A Yes, sir.

THE COURT: Is there any dispute about these hospital bills, Mr. McAfee?

MR. McAFEE: No.

THE COURT: No dispute about them.

MR. McAULEY: Very well. If I may have the list.

THE WITNESS: Okeh.

MR. McAULEY: (Writing on blackboard) Doctor Shoemaker, $5.00; St. Mary's Hospital, $120.40; Doctor Acker, $142.00; drugs and medicines, $35.00.

By Mr. McAuley:

Q Now, Mr. Kidd, let me ask you, what were you earning in 1953, your annual earnings? As I understand you did not draw a salary or work on a regular pay job: you built houses and did contracting work?

A That's right.

Q All right, sir, what was that?

(24) A You mean, you want the actual earnings in 1953?

Q Yes.

A Well, I earned $6,642.25.

Q What were your earnings for 1954? That is the actual earnings, not what was reported as gross earnings for income tax, but the actual work done.

A Actual work done was $2,900.00.

Q Twenty-nine hundred even?

A Yes, sir — $2,973.00, I beg your pardon.

Q A difference of the two years of $3,669.00?

A That's right, sir.

Q Roughly, $305.00 a month?

A Yes, sir, that is about right.

Q What time in April, 1954, was it that you resumed your regular work?

A No, April.

Q Of this year?

A Around the first of April, 1955.

Q That you did your first work for an income?

A Yes, sir.

Q And did you do any work from May, 1954, until April, 1955?

A Not to earn anything, no, sir.

Q Roughly, eleven months?

A Yes, sir.

(25) Q Did you lose any time in August?

A Of this year I lost two weeks.

Q Tell us, Mr. Kidd, whether or not you have been limited in any of your activities since contracting this disease? Can you do a full day's work like you did before?

A No, sir, I give out. I work in pain all the time.

Q What about your work on building houses; are there

some things you can't do that you were able to do before your disease?

A. Yes, sir, there is a lot of them I can't do.

Q Could you tell us a few of them?

A Well, I can't lift heavy rafters or two by six's or put up sheetrock overhead, or anything like that.

Q Who does that kind of work?

A Well, I have two boys, or two men rather, that does that work for me.

Q You more or less supervise that?

A Yes, sir, and I do the light work, what I can do without putting too much strain on me.

Q Could you give the jury and court an idea as to your relative efficiency as a workman as compared to what it was before the disease hit you? Can you work full blast half-blast or two-thirds or what?

A About half blast.

MR. McAFEE: Let the witness testify. Don't lead, (26) Mr. Counsel – putting the answer in his mouth.

THE COURT: That is a little leading.

MR. McAULEY: Very well, your Honor.

By Mr. McAuley:

Q I will ask you if you have any way of comparing your current capacity to do work and labor now percentage-wise as compared to the way it was before you got the disease?

A Well, I can't hold out now, oh, about four or five hours, and I am just so weak and tired I can't make it.

Q How many hours could you go before the accident? I mean, before – still thinking of the accident – before the disease?

A Well, I could work ten hours a day and never know I was tired.

Q I believe that answers it. State whether or not you are currently under the care of a doctor?

A Yes, sir.

Q Who is that?

A Doctor Acker.

Q State whether or not you take medicine of any kind.

A Yes, sir, I take two kinds of medicine.

Q How often?

A Every day.

(27) Q Do you, of your own knowledge, know what they are?

A No, sir.

Q Is it a liquid or pill?

A One of them is a capsule and one of them is a pill. But it is something to stimulate your liver and keep the bile moving, or whatever they call it, as it should.

MR. McAULEY: I believe you can ask him.

CROSS-EXAMINATION

By Mr. McAfee:

Q How old are you, Mr. Kidd?

A Forty.

Q Forty years of age?

A Yes, sir.

Q I show you here, Mr. Kidd, a surgical or medical permit dated 3-8-54 signed by Mrs. Floyd Kidd at the time you entered St. Mary's Hospital.

A Yes, sir.

Q That is your wife's signature?

A Well, it looks like it.

Q And she had authority to sign this permit for you?

A Yes, sir, I guess so. It looks like her handwriting.

Q But anyway, you approve her signing this permit for you?

(28) A Well, I would have if she had asked me; yes sir.

MR. McAFEE: I want to read this, if your Honor please, to the jury.

THE COURT: Yes.

MR. McAFEE: (Reading) "I, the undersigned, a patient or friend of patient of Floyd Edgar Kidd at St. Mary's Hospital, hereby consent to any surgical or medical procedure the surgeon or physician may deem necessary. Signed, Mrs. Floyd Kidd."

By Mr. McAfee:

Q Mr. Kidd, can you describe the wound that you suffered?

A Sir?

Q Can you describe to the jury the wound that you suffered when you were working there on the house and struck by the saw?

A Yes, sir.

Q How long was it?

A Well, I guess it was around eight or ten inches maybe.

Q How deep was that wound, Mr. Kidd?

A Well, I couldn't tell you exactly how deep it was, but it was not to the bone.

Q Well, your doctor then would know more about that, wouldn't he?

(29) A Yes, sir.

Q The doctor that actually treated you there?

A Yes, sir.

Q You lost quite a bit of blood, hadn't you, Mr. Kidd?

A Well, I imagine I did. It did not appear to bleed too much, though.

Q Now, you were suffering quite a bit of pain?

A Well, it hurt a little bit. Sure did. After it hap-

pened, it hurt worse later. When it was first cut I didn't notice it too bad.

Q The pain came a little later?

A Yes, sir.

Q At the time there, the first day, you said you took some shots?

A When I entered the hospital, yes, sir.

Q How many shots did you take, do you know?

A No, sir, I couldn't tell you.

Q Do you know whether or not you took a shot for, an antitetanus shot?

A Well, they gave me something. I don't know what they were for.

Q Where did they give those shots to you?

A Down in the receiving ward.

Q I didn't understand you?

(30) A Down in the receiving ward.

Q What part of your body, where did they put those shots, in your arm or in your leg?

A Put them in my arm.

Q You were shot several times there in the emergency ward, weren't you?

A I think about three times, maybe.

Q Three times?

A Yes.

Q All three of them in your arm?

A No. They gave me one in my hip.

Q Put one in your hip?

A Yes, sir.

Q Do you know what that one was?

A No, sir.

Q You were in the hospital how long the first time?

A About nine days.

Q You were in the hospital about nine days the first time?

A Yes, sir.

Q During that nine days did you receive other shots, all different kinds?

A Yes, sir.

Q With a needle?

A Yes, sir.

(31) Q How often did they give you your shots?

A Well, for the first two days they gave me shots every day.

Q Every day?

A Yes, sir.

Q And how many a day?

A Well, one or, maybe one or two a day. I didn't keep any count of them.

Q All right, sir.

A But then after a couple of days they begin to let up on it to maybe every other day, and finally they tapered off on the last week and they didn't give me any shots at all the last week I was there.

Q But you were given quite a few shots?

A For about four or five days, yes, sir.

Q When you were first in the hospital?

A Yes, sir.

Q Now, when you left the hospital after that, nine days, what did you do?

A I went home.

Q And you worked some between the time after you got home, between May before you went back to the hospital the second time?

A Yes, sir, I worked just a little bit.

Q What did you do?

(32) A Well, just looked after what work I had. Going along.

Q Did you have any pain during that time with your leg?

A No, sir.

Q Take any shots in between times?

A No, sir.

Q Didn't?

A Didn't take any.

Q Did you stay in bed during any of the time after you went home?

A For the first couple of days I just laid down and rested on the bed.

Q And the next time after you got home, you went to work doing little odd things about building your house?

A Yes, sir.

Q I believe you said you were building this house for yourself?

A Yes, sir, on Carson Avenue.

Q Where?

A On Carson Avenue.

MR. McAFEE: I believe that is all. I would like for you to show the jury though before you leave, if you will, just take your coat off and show the jury – I am sure they couldn't see the tatooing on your arm from the distance (33) you were sitting. Will you show it to them as you pass by, please, sir?

THE WITNESS: Yes, sir.

(Witness complies with request of counsel)

THE COURT: Is that all for this witness?

MR. McAFEE: Yes, your Honor.

THE COURT: Take a short recess.

(A short recess was had.)

Harry K. Wood, Jr.

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q This is Mr. Harry K. Wood?

A Junior.

Q Junior?

A Yes, sir.

Q Mr. Wood, what is your occupation?

A I am chief pharmacist at St. Mary's Hospital.

Q How long have you been the chief pharmacist at St. Mary's Hospital?

A Twenty years.

Q Mr. Wood, what do you have to do with the buying of the pharmaceuticals at the hospital?

(34) A I do all the buying of the pharmacy department. All the drugs are bought by me.

Q What kind of blood plasma is used there at the hospital, and I will say what kind was used in March of 1954?

A We have used the same type of plasma for twenty years. It is manufactured by Sharp & Dohme Laboratories and is irradiated plasma.

Q Who is it that you purchase that from and who calls on you?

A Mr. Paul Robinson, Knoxville, Tennessee.

Q And what company does he represent, do you know?

A Sharp & Dohme.

Q Does he represent the Merck & Company, Incorporated?

A Well, Merck, you know — Sharp & Dohme is a division of Merck.

Q Sharp & Dohme is a division of Merck?

A That's right.

Q And that is the only plasma that the hospital has used?

A That is the only one I have ever kept.

Q And that plasma was available there at the hospital in March of 1954?

A Yes, it was.

MR. McAULEY: You may ask him.

(35) CROSS EXAMINATION

By Mr. Coburn:

Q You have been the chief pharmacist there for twenty years?

A For twenty years.

Q It doesn't seem possible.

A I started there when I was ten years old.

Q I believe that you said that during this period you had always bought Sharp & Dohme blood plasma.

A I have.

Q Was there any particular reason for that?

A Well, I chose that particular plant because it is in dry form and is irradiated, so therefore you don't have any chance to have it spoil. Also, the representative from Sharp & Dohme is a resident of Knoxville and I have a chance to see him in a hurry if anything goes wrong. He also checks my file every two weeks, which is as often as it should be checked to keep it in good standing, and I figured that was the best thing for the safety of everyone concerned.

Q You have used it for 20 years. I take it you have

not had to check with him too much because something went wrong.

A I have never had anything wrong in all that time.

Q How much plasma do you usually keep on stock?

A I keep eight units.

(36) Q Eight units?

A Yes.

Q And each unit is – three in one pack?

A That's right. Sometimes you give two if the patient is very ill.

Q I suppose if there were a serious accident or something of that sort in the area you might exhaust all that supply?

A I have on occasion.

Q What did you do then?

A In that case I called the representative and he wired to Atlanta for it and it is brought here by air.

Q You have never had occasion to have to borrow from another hospital?

A Not plasma, I haven't.

Q Then, as I understand it, in all this twenty years' history of using Sharp & Dohme plasma, this particular complaint is the only one you have had concerning the use of plasma?

A The only one I know of.

Q You would know of it?

A Certainly, they come to me first.

MR. COBURN: Thank you.

REDIRECT EXAMINATION

By Mr. McAuley:

(37) Q In other words, it is a very rare, rare disease, isn't it, Mr. Wood?

A I don't think it is so rare. So many fellows got it during the war.

Q I beg your pardon?

A You mean hepatitis?

Q Yes, from plasma.

A Oh, from plasma. Well, from this particular plasma I think it should be because this plasma is irradiated.

Q That would make it rarer?

A I think so.

MR. McAULEY: That is all. Thank you.

MR. COBURN: That is all.

(Witness excused.)

Milton Norris

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q You are Mr. Milton Norris?

A That's right.

Q Mr. Norris, what is your occupation?

A I am the chief technician, St. Mary's Hospital.

Q And what is your age, please, sir?

(38) A Forty-six.

Q Do your duties include injecting needles in patients, taking blood samples, and the like?

A My only duties on that would be take blood samples. As far as injecting anything, I do not.

Q Inserting the needle and withdrawing blood?

A That is all.

Q And, in that connection, of course you do use needles

A That's right.

Q Could you tell us, Mr. Norris, what, if any, system the hospital, in your department particularly, employs in connection with sterilizing needles?

A Well, of course, the needles are washed thoroughly with water and a detergent to remove any foreign body or foreign material, and after they are completely washed, alcohol is run through them and they are packaged separately, put the needle and syringe in an autoclave and sterilize them 30 minutes at 20 pound pressure.

Q Then, I will ask you this: After having given the needle that particular treatment, is that needle used more than once before it is again sterilized?

A Just used for the one time and recleaned and resterilized.

Q It is recleaned and resterilized after each use?

(39) A Yes, sir.

Q And was that the practice of March, 1954 also?

A That has been the practice at the hospital from the time I have been there.

Q And you have been there how long?

A Since 1949.

MR. McAULEY: You may ask him.

CROSS EXAMINATION

By Mr. Coburn:

Q You are the chief technician, I believe you said?

A Yes, sir.

Q And I think you said your duties are supervising only the taking of blood samples from the patients who might be at the hospital?

A That's right.

Q Now, if the patient who was at the hospital received various injections of morphine or demerol or other material

that is, that a patient might be receiving by hypodermic means, do you have any responsibility for that work?

A None at all, sir.

Q No responsibility for the sterility of the equipment used in that connection?

A No, sir, nothing to do with our department at all.

Q Are you familiar with the minimum requirements of the National Institute of Health for withdrawing whole blood (40) citrating whole blood dealing with the sterilization of instruments?

A No, sir.

Q Are you familiar, at least by reputation, with Doctor Roderick Murray, who is associate director of the National Institute of Health?

A The only thing I am familiar with in the administering of blood is that we receive our sets and they are not dispensed from our department. The only thing I have anything to do with is drawing the blood from the donors or from patients. As far as administering, I have nothing to do with it.

Q Would you agree that whatever requirements are set forth for the sterilization of instruments used in the actual withdrawing of blood for donor purposes would also be acceptable standards to be followed when you sterilize the instruments for drawing blood in your department for sampling?

A I would think so; yes, sir.

Q What are the conditions under which you sterilize your needles?

A I sterilize them in an autoclave of live steam at 20-pound pressure for 30 minutes.

Q Thirty minutes?

A Yes, sir.

Q Mr. Norris, you gave a deposition on oral examination (41) in this case, did you not?

A Yes, sir.

THE COURT: Mr. Norris, I believe, Mr. Coburn, if you will stand back a little the jury can hear. He drops his voice. Talk up, Mr. Norris, because the jury wants to hear what you say.

By Mr. Coburn:

Q I ask Mr. Norris if he hadn't given a deposition on oral examination in this proceeding, and you said that you had?

A You mean the one at St. Mary's Hospital?

Q Yes, sir.

A Yes, sir.

Q You were asked there a question of how you prepared the needles and other equipment, and you said, "We use a sterile syringe to collect our sample of blood. We sterilize it under steam pressure at 20 pounds for 15 minutes; which is the accepted rule for sterilizing equipment;" is that a correct statement?

A I can't remember what I said, 15 minutes or 30 minutes. I may have said 15 minutes. I think 15 minutes will sterilize them but I am pretty sure we sterilize ours 30 minutes to make absolutely sure of it.

Q Why are you more sure of it now it was 30 minutes than you were when you said 15?

(42) A I am not sure. I may have said 15.

Q And, as a matter of fact, you knew you were using 15 minutes?

A We may, but 15 minutes will sterilize them.

Q Since you said you are not familiar with the minimum requirements of the National Institute of Health in connection with the sterilizing of instruments, I assume

you would not know whether the procedure you follow for sterilizing was within the standards or not?

A I have never read them.

Q So, you don't know whether the sterilizing procedure you follow meets those standards or not?

A I don't know whether the time does or not, 15 or 30 minutes. Since I have worked in laboratories 15 minutes is ample time to sterilize them at 20 pounds pressure with live steam.

Q But how long ago was that?

A I have been doing laboratory work for about 20 years.

Q And it is quite possible the requirements now for sterilization of needles against hepatitis developing might require a greater length of time than 15 minutes?

A That, I couldn't tell you. I don't know.

THE COURT: Can you hear the answers, ladies and gentlemen? Mr. Norris, the jury wants to hear what you say (43) and I will have to ask you to talk louder.

Will you read the last question and the last answer. I don't know whether the jury heard it or not.

(The preceding question and answer were read.)

MR. COBURN: That is all.

REDIRECT EXAMINATION

By Mr. McAuley:

Q Whether 15 or 30 minutes, Mr. Norris, in any event I believe you did indicate that 15 minutes would definitely sterilize instruments?

A That is what I have been told, 15 or 30 minutes would with that much steam pressure.

Q Twenty pounds pressure of live steam?

A That's right.

Q St. Mary's Hospital is one of the outstanding hospitals, is it not, in this area?

A I suppose so.

MR. McAULEY: That is all.

RECROSS EXAMINATION

By Mr. Coburn:

Q Just one question. That is what you were told 20 years ago?

A That is what I have always been taught; yes, sir.

(Witness excused.)

MR. McAULEY: Now we have, if your Honor please, (44) the deposition of Doctor Gunn.

I might say this is the deposition of Doctor W. U. Gunn, which was taken last October 8, at Louisville, Kentucky, Doctor Gunn being the person there in the receiving ward who started the plasma.

(Whereupon, the deposition of Doctor W. U. Gunn was read by counsel: Mr. Marsh reading the questions and Mr. McAuley reading the answers.)

Dr. W. U. Gunn,

called by the plaintiff, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposed as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q You are Dr. W. U. Gunn?

A Yes, sir.

Q Dr. Gunn, where are you presently located?

A With the Veterans Administration Hospital in Louisville, Kentucky.

"Q Will you give us your educational background, Dr. Gunn?

"A I was graduated from the University of Louisville Medical School in 1949 and served a year of interneship and I have had approximately three years experience in orthopedics.

"Q You limit your practice to the field of orthopedic surgery?

(45) "A At the present time I am with the staff of the Veterans' Hospital and I no longer do orthopedic service because of a physical disability.

"Q Where did you take your interneship?

"A At Orange Memorial Hospital in Orlando, Florida.

"Q Where were you located in March of 1954?

"A I was in Knoxville, Tennessee at St. Mary's Hospital.

"Q What was your connection with St. Mary's Hospital?

"A I was Resident Surgeon in Orthopedics.

"Q Were you in private practice or did you receive remuneration from some source?

"A I was connected with the hospital, not in private practice.

"Q And you were paid for your services by the hospital?

"A That's right.

"Q While you were there, Dr. Gunn, I will ask you whether or not you had occasion on March 8th, 1954 to see and treat a Mr. Floyd E. Kidd who is the plaintiff in this case?

"A Yes, sir.

"Q Where did you see Mr. Kidd?

"A I first saw him in the Emergency Room of St. Mary's Hospital.

"Q Would you remember what his condition was at the (46) time you saw him and what he was suffering from?

"A The man had just suffered an extensive laceration of the right thigh in an accident, in a saw accident. He was in extreme pain; in mild to moderate state of shock.

"Q What was done for him; had he been bleeding from the wound?

"A Yes, sir.

"Q What measures were taken at that particular time, Dr. Gunn?

"A The routine supportive measures that are usually administered with such an extensive injury were given. The man was admitted to the hospital. He was prepared for surgery. X-rays of the affected extremities were taken. He was given tetanus and gas-gangrene antitoxin. He was given streptomycin and penicillin and plasma was started intravenously.

"Q Was the plasma started there in the Emergency Room?

"A Yes, sir.

"Q And that was before the x-rays were made?

"A Yes, sir.

"Q What type of plasma was he administered?

"A He was given Lyovac, which is the trade name for Winthrop Stern's plasma.

"Q And who was the manufacturer of that plasma?

(47) "A Winthrop Stern.

"Q Was that Lyovac normal human plasma?

"A Normal human pooled plasma.

"Q Do you remember while there at St. Mary's Hospital seeing packages of Sharp and Dohme's plasma I believe it is called?

"A I have a correction."

MR. McAFEE: If your honor please, that was the attempt by adversary council to put the answer to this question in the witness' mouth, and I object to it and I think that objection should be sustained.

THE COURT: All right, read the objection.

MR. McAULEY: The objection is: "Just a minute, Doctor, please; the foregoing question is objected to because it is leading and suggestive."

He does not answer right there, your Honor.

MR. McAFEE: He goes on:

"MR. MARSH: Go ahead and answer, Doctor.

"Q Dr. Gunn, I believe you stated a moment ago that you had a correction to make. Would you make that correction for us now?

"A This product is Lyovac. I think I made a statement that it is Sharp & Dohme's. I believe it is Winthrop Stern's is Lyovac plasma.

"Q Was it the plasma that was furnished by the (48) Pharmacy Department of the St. Mary's Hospital?

"A It was furnished by the Pharma y Department and I am positive it was Lyovac.

"Q Aren't you also positive that it was Sharp & Dohme's?"

MR. McAFEE: There, again, your Honor please, he put the answer—

THE COURT: Do you deny about selling this?

MR. McAFEE: No. But I object to counsel leading his witness.

THE COURT: Overrule. Do not bring up matters of that kind.

"THE WITNESS: It is Sharp & Dohme's, Lyovac is.

"Q How is that material or that plasma packaged, Dr. Gunn?

A It is under a strict packaged sterile condition. It is wrapped in a sealed box, a cardboard package and the bottle in turn is sealed with a heavy aluminum package.

Q How many bottles come in the package?

A Two bottles.

Q One contains what and the other what?

A One is a vacuum, empty bottle and the other bottle contains dried plasma product.

Q Is one mixed with the other?

A That's right.

(49) Q Do you remember the name or could you by referring to a note tell us who the nurse was who assisted at this administration of the plasma?

A Mrs. Mildred Wolfe.

Q Was the patient placed on a hospital bed or on a table?

A On a treatment table.

Q He was placed on a treatment table?

A Yes.

Q Was anything done about the thigh wound there in the Emergency Room or was that done later on in his hospitalization — in his hospital room?

A The wound was merely dressed in the Emergency Room.

Q How did you go about starting the plasma? How is that done, the mechanics of it? You open the package and—

A The package is opened, broken and the double needle, which is part of the package, is inserted into the vacuum bottle and the other end is inserted into the plasma product bottle and the venipuncture needle is in turn inserted into the vein of the recipient.

Q What connects the venipuncture needle to the bottle of the prepared plasma?

"A A sterile needle which is supplied with the package.

(50) "Q I will ask you whether or not there is a tube?

"A Oh yes, there is a plastic tube which is also supplied with the package.

"Q Is the bottle of plasma elevated above the patient?

"A Yes, sir.

"Q And the contents of the bottle of plasma pass through the tube into the needle and into the patient's vein?

"A Yes, sir.

"Q Dr. Gunn, I will ask you whether or not the package is a sealed package?

"A It is sealed.

"Q What method is employed in opening that package or is it accompanied with any difficulty?

"A Only moderate difficulty. It can be opened by hand.

"Q Is the package such that had it been previously opened or tampered with that you could have told that by inspecting it?

"A Yes, sir.

"Q Was this a sealed package?

"A It was sealed.

"Q Can you tell us whether or not Mr. Kidd's stay in the hospital was relatively uneventful or rather, I will ask (51) you what was his progress?

"A After he was taken to surgery he had an uneventful convalescence and was discharged a few days later.

"MR. McAULEY: I believe you may ask.

CROSS EXAMINATION

"By Mr. McAfee:

"Q Doctor, how long did you stay there at St. Mary's?

"A Two years.

"Q When did you start?

"A In January of 1953.

"Q And you left?

"A I left in October of '54.

"Q. During that period of time you were the resident surgeon there at the hospital?

"A Yes.

"MR. McAULEY: In orthopedics.

"THE WITNESS: The orthopedic service, yes.

"Q Now, you mentioned something a while ago about Winthrop Stern's plasma. They do make a plasma do they?

"A No, sir; I believe not. This product — I am positive it was Lyovac.

"Q What makes you positive, Doctor?

"A Because I remember distinctly seeing Lyovac and it was all that was available at St. Mary's.

"Q Could you be mistaken about it, Doctor?

(52) "A No, sir.

"Q You couldn't. What makes you remember this particular episode so distinctly, Doctor? I notice you don't have any notes of any kind in front of you there. Why do you—

"MR. McAULEY: (Interrupting) I would like to state for the record that the doctor is testifying from a photostatic copy of the Emergency Room record.

"MR. McAFEE: Well, I didn't know that. You didn't tell this.

"Q. Doctor, this photostatic Emergency Room record you say you have been testifying from that as to these facts?

"A Only partially, to help me recall, because as you suggested, there are a great many emergencies that are admitted there from time to time. This is my own handwriting at the time though, part of this Emergency Room record.

"Q Who ordered the plasma to be given Mr. Kidd?

"A I did.

"Q For what purpose did you give it to Mr. Kidd?

"A Because of his mild shock state and also because it was anticipated that he would be immediately taken to surgery and that is the routine method to start an intravenous transfusion in the Emergency Room to anticipate their being taken to surgery.

"Q Is that the common accepted practice of treatment (53) in cases of this kind when they suffer just like Mr. Kidd?

"A When the injuries are this severe, yes, sir.

"Q Could you describe for us just the type of an injury that Mr. Kidd had?

"A He had approximately a 14 to 16 inch laceration on the anterior right thigh which extended down to the entire soft tissue layer to the bone.

"Q Quite a severe cut, wasn't it, Doctor?

"A It was severe, jagged, a dirty cut.

"Q And you gave him the plasma because of the shock condition the patient was in?

"A Yes, sir.

"Q Is that the only reason?

"A Well, the reason also that I gave a while ago is that he was going to be taken to surgery and it is usual to have an intravenous needle started at the time and also to draw his laboratory blood.

"Q So that to – well, is that to replenish the blood too, is that the purpose of that?

"A For possible replenishment.

"Q Doctor, you said this particular package of plasma that you used was in a sealed box?

"A Yes, sir.

"Q You have given plasma often, haven't you, Doctor?

"A Yes, sir.

(54) "Q You—of course have read the instructions that accompany plasma, by the companies?

"A Yes, sir.

"Q And especially the instructions that accompanied the Lyovac plasma?

"A Yes, sir.

"Q You read those?

"A Yes, sir; I have read them before.

"Q Doctor, I hand you here some printed instructions which is issued by Sharp & Dohme and it accompanies every package of Lyovac Normal Human Plasma. Have you seen the printed instructions like that in the plasma used there at St. Mary's Hospital?

"A Yes, sir; I have.

"Q Have you read those instructions, Doctor?

"A Yes, sir.

"Q Now, Doctor, I will ask you if there is any scientific procedure or method of discovering whether or not whole blood or blood plasma contains a hepatitis virus?

"A At which time are you referring?

"Q At the time of taking blood from the donor or any time before the transfusion is given?

"A Not to my knowledge.

"Q There is no scientific method or procedure that you know of, of discovering whether or not whole blood or (55) blood plasma contains a hepatitis virus?

"A That is a little out of my field, and they may have methods.

"Q But you don't know of any?

"A I wouldn't know myself.

"Q Doctor, isn't it a fact, a well-recognized fact by the medical profession throughout the country that in

all cases of transfusions of whole blood and blood plasma there is always the possibility of the patient contracting hepatitis or a jaundice?

"A It is a so-called calculated risk.

"Q You say that is a calculated risk, then, that each patient takes when you give transfusions of whole blood and blood plasma?

"A It is a risk, yes, sir.

"Q And you knew that that was a risk at the time you gave this particular plasma to the plaintiff Kidd?

"A Yes, sir; I didn't think of it as a risk, however.

"Q But you knew about the risk at the time you gave this plasma to the plaintiff Kidd?

"A Yes, sir.

"Q Now, I believe you stated that you were the one that actually supervised the transfusion of the blood plasma to the plaintiff Kidd on this particular time on March—

MR. McAULEY: The witness testified he did it (56) himself.

"Q You did it yourself?

"A That's right.

"Q All right. Now, I believe your stated that you have read those instructions and directions which accompany the Lyovac plasma prepared by Sharp & Dohme and I would like for you to file this pamphlet as Exhibit Number One to your deposition?

"A I do.

"(Thereupon the document above referred to is filed herewith as part hereof.)

"Q Now then, Doctor, I want you to turn to page two of the pamphlet and read into your deposition there beginning at the bottom of the page where it says "Risk of Serum Hepatitis" on page two, down to the end of page three."

THE COURT: Do you want the exhibit filed?

MR. McAFEE: Yes.

(Exhibit No. 1 was filed.)

MR. McAULEY: This is reading from the pamphlet which is enclosed with each package of plasma.

"A — It is generally recognized that some samples of human blood contain a virus capable of causing so-called serum hepatitis or serum jaundice following transfusion. Although the relationship of homologous serum hepatitis to infectious hepatitis is not entirely clear, present (57) indications are that the icterogenic agent of both diseases is a virus.

"Despite careful selection of blood donors under strict supervision, there is still the possibility that some blood will contain the hepatitis virus, since no laboratory procedure exists for its detection in the blood.

"In recent years methods have been developed for the sterilization of suspensions containing bacteria and viruses. In controlled studies carried out in human subjects, using both irradiated and nonirradiated serum, hepatitis did not occur in those individuals who received injections of irradiated material. Toxic effects due to radiation of plasma were not observed following injection of this material and there was no deleterious effect on the therapeutic value of the plasma. Radiation of plasma with ultraviolet light was accordingly adopted as a requirement by the National Institutes of Health.

"More recently, similar controlled studies in human subjects were carried out using plasma irradiated with ultraviolet light in compliance with the regulations of the National Institutes of Health. In these new studies the radiation process was not effective in preventing the transmission of homologous serum hepatitis.

"In addition to the studies referred to above, there have been several reports of hepatitis following the (58) injection of irradiated human plasma in which, despite other well recognized sources of infection, it appears that the virus was transmitted through the plasma. The occurrence of serum hepatitis has also been reported following the injection of irradiated human mumps immune serum.

"On the basis of the limited evidence now available, the physician should assume that the use of irradiated human plasma still may involve a calculated risk that the patient may develop serum hepatitis."

Q Doctor, the instructions that you have just filed bear number M-96207. That is correct, isn't it?

A That is the number on the pamphlet you have here.

Q Yes. Now I show you another pamphlet which bears number 96204 – M-96204 and I am going to ask you to file that pamphlet as an exhibit, Exhibit Number Two of your deposition?

A I do.

(Exhibit No. 2 was filed.)

Q Now, then, I call your attention to page two of the pamphlet you have just filed as Exhibit Number Two to your deposition, beginning with page two at "Risk of Serum Hepatitis" I am going to ask you to read that into your deposition?

A "It is generally recognized that some samples of human blood contain a virus capable of causing so-called (59) serum hepatitis or serum jaundice following transfusion. Although the relationship of homologous serum hepatitis to infectious hepatitis is not entirely clear, present indications are that the icterogenic agent of both diseases is a virus. The reported morbidity rate of serum hepatitis varies from 1.5 per cent among patients who re-

ceive plasma from small pools (5 to 10 donors) to 4.5 per cent to 12 per cent in patients receiving plasma from large pools (1000 to 5000 donors).

"Despite careful selection of blood donors under strict supervision, there is still the possibility that some blood will contain the hepatitis virus, since no laboratory procedure exists for its detection in the blood.

"In recent years methods have been developed for the sterilization of suspensions containing bacteria and viruses. In controlled studies carried out in human subjects, using both irradiated and nonirradiated serum, hepatitis did not occur in those individuals who received injections of irradiated material. Toxic effects due to radation of plasma were not observed following injection of this material and there was no deleterious effect on the therapeutic value of the plasma. Radiation of plasma with ultraviolet light was accordingly adopted as a requirement by the National Institutes of Health.

"More recently, similar, as yet unreported, con- (60) trolled studies in human subjects were carried out using plasma irradiated with ultraviolet light by a technique complying with the regulations of the National Institutes of Health, but differing in some respects from that employed in the original studies and that employed in the manufacture of "Lyovac" Normal Human Plasma. In these new studies the radiation process that was used was not effective in preventing the transmission of homologous serum hepatitis.

"In addition to the studies referred to above, there have been several reports of hepatitis following the injection of irradiated human plasma in which, despite other well recognized sources of infection, it appears that the virus was transmitted through the plasma. The occurrence of

serum hepatitis has also been reported following the injection of irradiated human mumps immune serum.

"On the basis of the limited evidence now available, the physician should assume that the use of irradiated human plasma still may involve a calculated risk that the patient may develop serum hepatitis."

"Q Now, I believe you said one of those pamphlets was in the package of plasma that you opened there to give to Mr. Kidd?

"MR. McAULEY: He said a pamphlet.

"A A pamphlet was and I don't know whether it was one of these. It was similar.

(61) "Q Well, it contained a provision anyway calling your attention to the risk of serum hepatitis, did it not?

"A I don't remember specifically.

"Q Haven't you read that pamphlet, Doctor?

"A I have read a similar pamphlet, but I can't remember whether that particular one – I didn't read the phamplet with that particular serum.

"Q But you have read a pamphlet?

"A Yes.

"Q Prepared by Sharp & Dohme and sent along with its plasma?

"A Yes, sir.

"Q That contained that same provision calling attention to the risk, of the calculated risk of hepatitis in the event plasma was used?

"A Yes.

MR. McAULEY: Let the record show that this witness has not in fact read the provision contained in either of these two documents.

"Q Well then, I will ask him to read it now. You read Doctor, the provisions in both of these pamphlets and see

you recall reading that in a previous pamphlet or a similar pamphlet?

"A Yes, sir; I have read similar information.

"Q All right. In the pamphlet prepared and that (62) accompanied the Sharp & Dohme's plasma?

"A Yes, sir.

"Q Doctor, how many different ways can a person contract serum hepatitis?

"A Well, there are several means.

"Q Give us some of them?

"A The first and most common is by pooled plasma, but there are records on cases where patients have had it without being given pooled plasma. I am not familiar with the others.

"Q Can you contract it from taking whole blood from another person?

"A That's right.

"Q Well, there are numerous cases, numerous sources where a person can contract serum hepatitis, aren't there?

"A I am not positive.

"Q Well, don't you know that you can contract it from taking these malaria vaccine shots?

"A I have heard that.

"Q Yes, that is a common source of it?

(Witness nodded head in affirmative.)

"Q Don't you know as a matter of fact that you can contract it from unsterilized needles when you inject it into your veins?

"A I have heard of that.

(63) "Q That is another common source of it, isn't that true?

"A Well, any source where you are introducing the possible production of another person's blood products.

"Q Have you ever known of hepatitis following dental procedures?

"A No, sir.

"Q Or have you ever heard of it following tattooing?

"A I have heard of it.

"Q You have?

"A Yes.

"Q Have you ever heard of it occurring in drug addicts?

"A As I said before, it can be caused by anything where–

"Q Where there is an injection into the arm or veins of the blood stream?

"A If it involves a second blood source.

"Q When a person enters St. Mary's Hospital or any other hospital he signs an entrance card which he approves and authorizes the hospital and the attending doctor to use such methods as he deems wise in caring for him. Isn't that true?

"A Well, if he is unable to one of his relatives does it.

(64) "Q One of his relatives?

"A At the earliest practicable moment.

"Q In other words he can – he consents to all of the treatments that are provided for him there in the hospital?

A If it is an emergency it is undertaken before the formal consent is arranged.

"Q Well, you don't know whether that was true in this particular case or not, do you?

"A I didn't witness the signature, no.

"Q You don't know as a matter of fact that his wife did sign the consent in his particular case?

"A No, but I assume that she did.

"Q Was she there at the time?

"A Yes, she was there.

"Mr. McAFFEE: That is all.

REDIRECT EXAMINATION

By Mr. McAuley:

Q Dr. Gunn, when Mr. Kidd came in I believe you described his condition as a mild to moderate shock. Is that right?

A Yes, sir.

Q A person that is in a mild to moderate shock, I will ask you if that is a critical thing? In other words are you sort of on the verge of dying or is it less than critical from the standpoint of being on the verge of dying?

(65) A It is not critical, no, sir.

MR. McAULEY: That is all.

RECROSS EXAMINATION

By Mr. McAfee:

Q But you thought it was advisable to give the plasma in this particular case otherwise you wouldn't have given it?

A That's right.

MR. McAFEE: Why don't we tear the page out? It is mounted on a page.

MR. McAULEY: Why not pass the whole deposition?

MR. McAFEE: It is stapled together. It has a picture of it in that. Right here it is, Mr. McAuley, on page 2.

MR. McAULEY: I know, but the whole pamphlet was introduced.

MR. McAFEE: I have another one.

MR. McAULEY: Why don't you give them a loose one?

THE COURT: Was the pamphlet read, read to the jury?

MR. McAULEY: I feel I read a good portion of it, your Honor.

THE COURT: All right.

MR. McAULEY: That is a picture of the stuff (handing to juror).

(66) Now, this is the deposition of Doctor J. E. Acker, Junior, which was taken on September 23, 1955. Doctor Acker being the physician who is taking care of Mr. Kidd. The questions will be read by Mr. Marsh and the answers by myself.

"The said witness,

Dr. J. E. Acker, Jr.,

being first duly sworn, deposed as follows on

"DIRECT EXAMINATION

"By Mr. McAuley:

"Q You are Dr. J. E. Acker, Jr.?

"A Yes.

"Q Where do you maintain your offices?

"A 205 Medical Arts Building, Knoxville, Tennessee.

"Q Will you please state your educational background, qualifications and memberships in any organizations and whether you have been certified by any Boards.

"A B.S., University of Tennessee, 1941, M.D., University of Tennessee, 1941, one years' internship, Kansas City General Hospital, Kansas City, Missouri, 46 months in the Navy as a medical officer, being discharged with the rank of Lieutenant Commander, Medical Corp.

"MR. McAFEE: We will admit the doctor's qualifications.

"By Mr. McAuley:

"Q Will you please continue?

(67) "A Residency, Internal Medicine, City Hospital, Cleveland, Ohio, April, 1946, through July, 1948. Private practice of medicine here since.

"Certified by the Medical Board of Internal Medicine, Associate American College of Physicians, Fellow American College of Chest Physicians, member of the Knoxville Academy of Medicine.

"Q Can you tell us whether you limit your practice to any particular field of medicine?

"A I limit my practice to internal medicine. More recently to cardiology.

"Q Have you had occasion to see and treat the plaintiff in this case, Mr. Floyd Kidd?

"A Yes, sir.

"Q When did you first see him, and where?

"A My consultation note is dated May 26, 1954.

"Q Where was Mr. Kidd at that time?

"A Room 328, St. Mary's Hospital, in Knoxville.

"Q What history, Doctor, was elicited?

"A This patient gave a history of having an extensive laceration of the anterior surface of the right thigh on March 8, 1954. He was treated at that time by the usual cleaning and sewing.

"He is alleged to have been in shock during his stay, or shortly after admission to the hospital and having (68) received a unit of plasma. He, so far as I was able to determine, had received no blood. The patient went well up until approximately two weeks before seen by me, at which time he kinda felt tired and noted slight nausea. He stated also his wife noticed a definite jaundice of his eyes, and the patient noticed his urine was becoming darker.

"He consulted Dr. Kenneth Shoemaker the day before, and was hospitalized.

"Q That completes the history, does it?

"A The significant history, yes.

"Q And now give the clinical findings.

"A Patient was a well nourished and well developed

male patient. He appeared jaundiced, moderately with jaundice of the skin or the sclera of the eyes. The liver was felt one finger below the right chest margin – costal margin, and was slightly tender.

"The remainder of the physical examination was not remarkable.

"Q What was the diagnosis at that time; or was there a diagnosis at that time, presumptively?

"A My initial impression was, probably homologous serum hepatitis.

"Q Was your diagnosis later on confirmed?

"A The liver function test confirmed the presence of a hepatitis. The diagnosis of the time in between is done (69) by history and related events.

"Q Will you please list the related events which were of significance to you in reaching this diagnosis?

"A From the history, the admission of the patient to the hospital approximately two months previously, at which time he received plasma, which is a known cause of serum hepatitis, and the subsequent development of jaundice within the usual incubation period following this, with the physical findings and laboratory function tests substantiating hepatitis, one may conclude that he is dealing with a hepatitis.

"Q And did you so conclude?

"A I did.

"Q Do I understand you first saw him on May 26th?

"A My consultation note is dated May 26th. I don't have it in this record I have here. I can find out from the girl the exact date when I first saw him.

"MR. KIDD: (Interposing) I think that is right.

"By the Witness:

"A I saw him the day following his hospital admission, I know.

By Mr. McAuley:

"Q And if the admission occurred on March 8, 1954, for which he was initially hospitalized, that would be a difference of some two months and 18 days?

(70) "A Right.

"Q Did I understand that the history was that immediately prior to the second period of hospitalization that is the one of May 25, 1954, that he had felt well until some two weeks before that admission?

"A Yes, sir.

"Q When he began to complain of a tired feeling and slight nausea?

"A Yes, sir.

"Q What is the incubation period for the serum hepatitus virus?

"A Sixty to one hundred twenty days.

"Q Is there a similar virus which produces a similar effect on a person?

"A There is a so-called infectious jaundice virus.

"Q What is the incubation period for that?

"A Fourteen to twenty-eight days. It is a much shorter period.

"Q On what occasions have you seen Mr. Kidd since that initial consultation of May –

"A You want all the dates?

"Q If it is handy, yes. When was he dischaiged from the hospital, might I ask?

"A May 30, 1954. Incidentally, could I make a correction?

(71) "Q Yes.

"A My initial visit to him was on May 25th, and not May 26th. Subsequent visits to my office have been on June 15, 1954, June 29th, July 13th, July 27th, September 7th, and November 16th. All of those were in 1954.

"February 16, 1955, June 17th, August 17th, August 23rd, 1955.

"Q I may have misunderstood, but did you say May 15, 1954?

"A May 25th.

"Q Was Mr. Kidd hospitalized at any time after the May, 1954 hospitalization?

"A Not to my knowledge.

"Q Could you tell us what his condition was or the progress that the disease took following discharge from the hospital in May, 1954?

"A His convalescence was slow, which is typical of this type patient, with the disappearance of marked, or of extensive laboratory findings, or not disappearance but with return of laboratory findings to normal or not normal positions — I mean office return visits on June 15th. However, there were the usual findings of fullness of the stomach, ease of fatigue, occasional vomiting, intolerance to certain foods, such as cabbage and beans.

"The patient was kept at home until approximately (72) the middle of July, at which time he was told to gradually increase his exertion.

"He did not return to work until some time around November, 1954. I don't have the exact date down here.

"Q I would like to ask if this condition as you have described is disabling, that is, would render one unable to carry on an active life, or active work?

"A Could you repeat that question?

"Q What I have in mind is, he was discharged from the hospital in May, and you say you kept him at home for a while. I was wondering why he was kept at home — could he have performed his usual duties, or was he kept at home for any other reason?

"A He was kept at home because we know activity

tends to cause a relapse of the hepatitis, and we wish to prevent it.

"Q By November then I believe he was resuming his regular activities?

"A I think that is the correct date.

"Q Will you tell us whether he had any difficulties after November of 1954?

"A He has continued to have some difficulty to date, both subjective and objective.

"Q In other words, you could actually find a reason for the complaints he described, that is, they were (73) objective findings?

"A Some.

"Q What were they, principally?

"A At times, some tenderness over the liver. A slight abnormality of one of the laboratory tests, which is compatible with a relapse.

"Q Just how does this particular virus affect the liver, one that has been pretty well indoctrinated with it, what happens to the liver, that is a victim of hepatitis virus?

"A You want that in medical terms, or not?

"Q Like to have it in lay language, so even I might understand it, insofar as it is possible.

"A Do you wish that from the first? From the beginning?

"Q Yes.

"A That is a difficult question to answer. With an acute infection of the liver by a virus, the actual liver cells become swollen, and if seen under the microscope, they are distorted, they lose their usual architecture, and as a result of this there is a backing up of bile, to use the term which you can understand, causing the jaundice, or a reflux of bile – small bile ducts backing into the liver causes jaundice.

The normal period of this acute inflammatory (74)
process will vary considerably, depending on a number of
things, for instance, how soon the patient went to bed.
There are many variables, depending on the amount of
infection and type treatment the patient gets. Normally,
within a month or less, the jaundice has disappeared. The
liver function tests may have returned to normal, or may
not have, depending on the severity of the disease, and
how the patient was treated.

There is a clearing up of the local inflammation in the
cells, with a certain amount of scar formation, certain
amount of regeneration of the liver cells, and destroying
cells or damaged cells, so that in similar cases one sees no
great evidence of permanent damage to the architecture.
The same may be true of the liver function tests, which have
occurred.

In other cases, more severe, this may persist — the find-
ings may persist for a varying period of time, or may pos-
sibly go on to develop permanent scar formation to form a
picture which is called sclerosis of the liver.

At the present time, in an individual who has been
approximately sixteen months with this condition, one
might find no objective evidence or no great amount of
objective evidence within the liver of previous disease but
again, one might find considerable.

Q Have there been periods of time when he was free
(75) from symptoms?

A I would say relatively so.

Q And following a period of time when he was rela-
tively free from symptoms, those symptoms would reappear,
is that correct, or a relapse?

A Could you re-state that?

Q I believe you have stated there were periods of
time Mr. Kidd was relatively free from symptoms, and

I take it following such a period of time, there would be a reappearance?

"A There has been, and one specifically.

"Q And when was that?

"A Three weeks—by history, approximately three weeks prior to his visit, which was on June 17, 1955.

"Q Now would the disease be considered to have been dormant during the period of time prior to the reappearance of those symptoms, in a sense?

"A One might say so.

"Q Would the reappearance of those symptoms be something unusual and out of the ordinary in cases of hepatitis virus, or something that might be more or less expected?

"A I would say not common, and not rare, something in between.

"Q Can you tell us what in your opinion the future (76) holds for Mr. Kidd with respect to a recurrence of symptoms?

"A I feel with proper care, he can be back to a normal existence. Most patients do. Most patients are back to a normal existence, the majority of the patients before now.

"Q Do you feel by virtue of the experience he has had that the disease he had, was the disease he had unusually severe, or more than the usual case, in view of the fact he still does present symptoms?

"A That is a difficult question to answer. More than the usual case?

"Q It is my understanding the majority of patients should be symptom free by this time, and since Mr. Kidd isn't, I was wondering if that would enable you to symptomize or characterize his case?

"A I wouldn't put him in the unusually severe group.

"Q More than the usual?

MR. McAFEE: The witness said more than usual but not in the class of unusual.

By Mr. McAuley:

Q Do you give Mr. Kidd any type of medication at the present time?

A Yes, sir.

Q What is it?

A Bilron capsule, as needed, and Donnatal capsules.

(77) Q The first is for what, and the second is for what?

A They are both to control his symptoms of indigestion, gas on the stomach, etc. The former being a bile salts preparation, and increases the flow of liver bile, therefore improving the symptoms, and the other prevents any spasm of certain muscles and guiding the activity of the stomach and intestines.

Q Does a decrease in the normal flow of liver bile—

A A marked decrease could; or it could, I should say.

Q Does the symptoms of serum hepatitis lead to a decrease of the flow of liver bile?

A It might.

Q Did it in this case, in your opinion?

A I can answer that yes or no, but it isn't going to answer your presumption. I could say it may have.

Q In any event, the medication which you have prescribed is to increase the flow of liver bile?

A Not necessarily.

Q Maybe I misunderstood your earlier answer.

A Would it be better if I would just explain that?

Q We just want to know what the situation is.

A There are certain symptoms we know follow cases of hepatitis which can be improved by the above medication. (78) They are not necessarily due to a marked

decrease in the flow of liver bile. There is more to it than that, therefore for me to say categorically that I am treating a decreased flow of liver bile, would be a most superficial statement. That is why I can't be definite.

"Q Can you give the Court and jury any idea as to how long Mr. Kidd will remain under such medication?

"A No, sir.

CROSS EXAMINATION

By Mr. McAfee:

"Q Doctor, I don't believe I remember how long you said you had been in the active practice here.

"A Since September, 1948, seven years.

"Q Cardiology is your specialty right now?

"A Heart diseases.

"Q Mr. Kidd, I believe you said you entered the hospital on May 26, 1954, and was released from the hospital on May 30, 1954, or a period of about four days, is that correct?

"A Entered on May 25th and discharged on May 30th.

"Q That would be five days?

"A Six days.

"Q Have you had a good many hepatitis cases in your professional career?

"A Several.

(79) "Q Is there any scientific procedure or method of discovering whether or not whole blood or blood plasma contains a hepatitis?

"A Yes, sir.

"Q What is that procedure?

"A I can't give you a detailed account. I am not a laboratory man, but there is a differential test whereby

infectious hepatitis serum can be differentiated from hepatitis serum.

"Q That isn't my question. Let me go over it very carefully and slowly. Is there any method, scientific or otherwise of discovering whether or not blood contains a hepatitis virus?

"A Blood?

"Q Yes, blood or blood plasma virus.

"A Yes.

"Q What is it, what is the method.

"A I couldn't give you the name of the method.

"Q How do you know there is such a method?

"A I have read it.

"Q Whereabouts?

"A It was in the American Journal of Medicine some time since 1950 in an article by Stokes, and beyond that I can't tell you because I am quoting from memory of two or three or four or five years.

(79a) "Q You are testifying, and it is not a catch question, but it is an important question — you are testifying to this Court and to this jury that there is a method of discovering whether or not blood or blood plasma contains hepatitis virus?

"A Yes, but no practical method.

"Q What do you mean by that?

"A Well, one might empty Norris Lake spoon by spoon. That is no practical method as compared with letting the water out in the locks. It can be done, but it is not of sufficient simplicity with regard to time and expense to make it practical.

"Q If I understand you right, you say there is a method in determining the virus?

"A Yes, sir.

"Q But you can't tell me what the method is?

"A Can't give the name.

"Q And you can't explain the method?

"A I cannot.

"Q Can you isolate this virus?

"A I can't.

"Q Is there any method to isolate it?

"A That I couldn't tell you.

"Q Dont you know as a matter of fact that there isn't any way to isolate it?

(80) "A I said that I couldn't tell you.

"Q I want to show you a public health report dated August 13, 1943, Vol. 58, No. 33 on the question of Jaundice Following Administration of Human Serum, and which was prepared by John W. Oliphant, Surgeon, Alexander G. Gilliam, Senior Surgeon, and Carl L. Lawson, Passed Assistant Surgeon, United States Public Health Service. This is a photostatic copy. If there is going to be any objection, I am going to have to get the original document. Can we agree we may introduce this photostat?

"MR. McAULEY: I haven't made any objection.

"Mr. McAfee:

"Q Have you ever seen this report?

"A No, not that I recall.

"Q Turn to page 1235 — I will ask you now to file this as EXHIBIT No. 1 to your testimony. Read me the third paragraph as it appears on that page.

"MR. McAULEY: We will object to introducing it through the mouth of this witness who has neither seen or read the article.

MR. McAFEE: I would like to file that as Exhibit No. 3.

THE COURT: What is the objection there?

MR. McAULEY: "We will object to introducing it

through the mouth of this witness who has neither seen or (81) read the article."

THE COURT: Well, are you testing the witness by your examination?

MR. McAFEE: Yes, your Honor.

THE COURT: It may be considered, ladies and gentlemen of the jury, as testing the knowledge of this Doctor Acker. It is not considered as substantive evidence in this case about the character of the virus, and so forth, about whether or not the virus may be discovered by laboratory methods. It is not substantive evidence on that point.

MR. McAULEY: We concede it could not be so discovered, but this is a matter of getting before the jury the testimony of some witness who was not present, through the mouth of a witness who neither seen nor heard of the pamphlet. He asked the witness to read it to the jury.

MR. McAFEE: But he isn't testifying, if your Honor please, that there is no method — this evidence is that there is no evidence. That is testing his knowledge.

MR. McAULEY: Well, he should bring that witness here.

MR. McAFEE: Counsel just now made the statement that they concede there is no known method of determining this virus.

MR. McAULEY: The presence of the virus.

MR. McAFEE: In the blood?

(82) MR. McAULEY: Yes.

MR. McAFEE: They concede that.

THE COURT: You do?

MR. McAULEY: Yes, your Honor. That was stated in the very beginning.

THE COURT: Well, then you take issue with Doctor Acker's testimony.

MR. McAULEY: I think he is mistaken about it. He says he is not a laboratory man.

THE COURT: Then, ladies and gentlemen of the jury, plaintiff does not contend that in this case that there is any method by which this virus may be detected in the blood, and so you will consider that admission as a fact, that there is no method. That is what you agreed to?

MR. McAULEY: Yes, sir, I stated that in the very beginning.

MR. McAFEE: If they concede that, I will withdraw the exhibit.

THE COURT: All right.

(Whereupon, the reading of the deposition was continued.)

"The Witness:

"A I see this. Could I comment on it?

"Mr. McAfee:

(83) "Q Yes.

"A In 1943 at the time this was written the knowledge of the medical profession with regard to homologous serum hepatitis was for all practical purposes in its infancy.

"Q Will you read that paragraph?"

MR. McAULEY: That was the same continuing objection.

MR. McAFEE: They have already conceded there is no known method.

THE COURT: Don't read that.

MR. McAFEE: I will withdraw that.

MR. McAULEY: What page are you on now?

MR. McAFEE: On page 16 now.

MR. McAULEY: I see.

MR. McAFEE: And then I undertook to show an

other article, which I will also withdraw. No need of introducing it. He did say he had seen this second article though:

MR. McAULEY: I don't object to reading the whole thing.

THE COURT: Inasmuch as there is no issue on that question, why take up the time of this Court and jury about it; there is no issue on it. Don't read it.

MR. McAFEE: There was still a third article which I will withdraw without going into it since they concede (84) there is no known method.

MR. McAULEY: Where are we now?

MR. McAFEE: On page 19.

(Whereupon, the reading of the deposition was continued omitting the portions referred to.)

Mr. McAfee:

"Q Isn't it a fact, well recognized by the medical profession that in all cases of transfusions the whole blood or blood plasma, that there is always the possibility of the patient contracting hepatitis, or a jaundice?

"A As of the time he had his transfusion?

"Q. Isn't that true, generally?

"A For whole blood, even to date, yes, for plasma, at the time this man had his, since, no.

"Q Explain the last part of your answer.

"A To my knowledge, since this man contracted his serum hepatitis, the method of keeping pool plasma for approximately six months before using it, has, for practical purposes, eliminated the possibility of contracting serum hepatitis.

"Q From plasma?

"A If it is kept for that period of time. That is subsequent to what we are talking about.

"Q What do you say back at the time this plaintiff, Mr. Kidd, took his?

(85) "A It was a calculated risk.

"Q That is what I wanted. I am going to ask you this question. In other words, there is a calculated risk that person must take when they receive a transfusion of whole blood or blood plasma that it might contain a hepatitis virus, and they might get a jaundice of hepatitis from it?

"A Lets say there was.

"Q There was at the time Mr. Kidd took his transfusion?

"A His plasma.

"Q And that was well known among the medical profession too, wasn't it?

"A Yes, sir.

"Q Have you ever actually administered a transfusion of plasma?

"A Yes, sir.

"Q Of course you don't know what plasma was given Mr. Kidd — what make?

"A No.

"Q How many different ways can a person contract hepatitis, — what sources?

"A Are we speaking of homologous serum hepatitis?

"Q Yes.

"A By the administration of blood or plasma by the (86) use of equipment, which is just what you want me to say, so I will go ahead and say it — by the use of equipment that has not been adequately sterilized or processed, by the use of material previously used on patients with hepatitis, without adequate subsequent sterilization, by the administration of certain vaccines, notably yellow fever vaccine, such as occurred during World War II.

"Q That is the cause of most hepatitis virus, isn't it?

"A I couldn't answer that.

"Q You couldn't deny it?

"A I wouldn't make a categorical statement yes or no on that. Don't feel I am qualified to answer it, not having made a statistical study, as such.

"Q Can you think of any other source you could contract it?

"A There are others, but those are the principal ones that come to mind at the moment. If you have others, I might say I agree.

"Q Many others?

"A I said there might be.

"Q What is the principal source of infectious hepatitis?

"A Water, food, contaminated feces, contact with other patients.

(87) "Q Could a person carry a virus hepatitis for a great length of time, and it would remain dormant?

"A Which type of hepatitis?

"Q Either one of them.

"A There is a so-called incubation period which does vary from patient to patient, that is why we say 14 to 28 days for virus, versus 60 to 120 for hemologous serum. Answering your question specifically, before that, I could not say.

"Q Do you know whether it is possible for a person to carry that hepatitis for a number of years?

"A I, personally do not know.

"Q Do you know anything about the history of blood plasma, how it came into existence?

"A Not in detail.

"Q Isn't it true that blood plasma was used extensively during the second World War to soldiers who were

wounded on the battlefield, and given transfusions when they couldn't get the whole blood?

"A Yes, sir.

"Q And it served a very, very useful purpose in those cases, didn't it?

"A Yes, sir.

"Q And saved many thousands of soldier boy's lives?

"A Yes, sir.

(88) "Q Why do you give plasma and blood transfusions?

"A Would you care to divide those?

"Q Why do you administer blood plasma to a patient, what purpose does it serve?

"A I personally haven't used it since I got out of the service.

"Q What about transfusions of whole blood?

"A Transfusions of whole blood are administered for the treatment of—you want what I have used it for myself?

"Q What is it principally used for?

"A Principally used to replace red blood cells.

"Q Where a patient has lost a lot of blood?

"A Where a patient has an inadequate amount of blood.

"Q Where he has bled a lot?

"A Not necessarily.

"Q They use it for people in extreme cases of shock?

"A Yes, sir.

"Q Know any other use they give it for?

"A We are talking about blood now?

"Q Whole blood or blood plasma?

"A It is administered for replacement of red blood cells. It may be administered for many reasons.

(89) "Q Did I understand you to say you had never given blood plasma to a patient?

"A Since I got out of the service, to my recollection.

"Q Are you familiar with the plasma manufactured by Sharp & Dohme named Lyovac?

"A No, sir.

"Q Are you familiar with that blood plasma?

"A No, sir.

"Q Have you ever seen that plasma?

"A No, not to my recollection.

"Q Were you in the army?

"A No, I was in the navy.

"Q Did you use plasma extensively in the navy when you were there?

"A I wouldn't say extensively. I used it on several occasions.

"Q The plasma you used, did they have a little booklet of instructions, calling your attention to the risk that was involved?

"A I couldn't tell you, because when I used it, it was in times of great stress, and we didn't bother looking at instructions. We all knew from previous knowledge it was a calculated risk.

"Q You know Dr. Brashear, Stevens and Bourkard here (90) in Knoxville?

"A Yes, sir.

"Q How do they stand with reference to their reputation?

"A High.

"Q Very fine doctors, aren't they?

"A Yes.

"Q Did I understand you to say a few minutes ago that you could ascertain a method of procedure from some of your medical books as to discovering virus in a blood donor or hepatitis virus in a blood donor?

"A I didn't say blood donor, I said in blood.

"Q Before it was given in a transfusion?

"A I believe I can.

"Q I am going to ask you to do that. I am going to ask you to find that method or that procedure, and for that purpose, and other purposes, and I am going to reserve further cross examination of this witness."

MR. McAULEY: There was no further cross examination.

MR. McAFEE: There was no further finding of any procedure either.

MR. McAULEY: We have a medical witness who is going into surgery at 1:30, and if we put him on at 1 o'clock it will be appreciated. I thought if we (91) adjourned until 1 we could get him on.

THE COURT: Is it an emergency operation?

MR. McAULEY: I don't know, your Honor.

MR. MARSH: He stated to me he had an operation scheduled at 1:30.

THE COURT: If it is not an emergency this jury ought to have more than an hour and five minutes for lunch. If it is an emergency I will adjourn.

MR. McAULEY: We will find out if it is.

THE COURT: All I want to know is will it affect the patient adversely if we adjourn here until 1:15. If it is going to jeopardize —

MR. MARSH: We can go ahead and put him on at 1:15. What we had to ask him won't take 15 minutes.

THE COURT: Ladies and gentlemen of the jury, of course throughout the trial of this case don't let anybody talk to you and you will not undertake to reach a decision until you have heard the evidence and the argument of counsel and the charge of the Court.

Gentlemen, if you have any special requests I wish you would get them to me. If you have any now I would like

to have them: if you do not have them now, get them to me as soon as possible, not later than soon after the testimony is concluded.

Adjourn Court until 1:15.

(92) (Whereupon, at 11:54 a.m., Court recessed for the noon hour until 1:15 p.m.)

(93) AFTERNOON SESSION

(Whereupon, at 1:17 p.m., Court reconvened and the following proceedings were had in the presence of the jury, to-wit:)

THE COURT: Call your next witness.

MR. McAULEY: We have two witnesses here who have not been sworn, your Honor.

(Whereupon, the witnesses were sworn, and the rule having been asked for, excluded from the courtroom.)

MR. McAULEY: If the Court please, I would like at this time to read into the record from the dictionary the definition of the terms "filthy" and "impure."

And for the record, I am reading from the new Merriam-Webster, Webster's New International Dictionary, Second Edition, Unabridged, Page 947, definition of the word "filthy." It has quite a few definitions and I will just read all of them, if the Court please.

"Filthy. 1. Defiled with filth; whether material or moral; nasty; disgustingly dirty; polluting; foul; impure; obscene. 2. "— in the other sense — "disgraceful; disgusting; low."

Synonyms. "Squalid, unclean, gross, licentious. See DIRTY."

Antonyms. "Clean. See IMMACULATE."

One of the definitions being impure I would now (94) like to read the definition of the word "impure."

"Impure. Not pure; specifically: a. Containing something which is unclean; dirty; foul; filthy; unwholesome; as, impure water or air. b. Mixed or impregnated with something extraneous, especially inferior; adulterated; as, impure drugs, food, etc.; an impure diamond. c. Of art, etc., mixed; bastard; as, an impure style of ornamentation. d. Unclean, in a ceremonial sense; not purified; hence, defiled; unholy; unhallowed. e. Unchaste; lewd; unclean; obscene; as, impure language or ideas. f. Not accurate; not idiomatic; as, impure Latin."

Antonyms. "Pure, wholesome, unadulterated; innocent, clean."

I believe it is the rule that the Court takes judicial knowledge of the standard works such as the dictionary.

Doctor Roy A. Wedekind, Jr.

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q You are Doctor Roy A. Wedekind?

A That's right.

Q Doctor, where do you maintain your offices?

(95) A Here in Knoxville.

Q And how long have you been a practicing physician?

A Two and a half years.

Q Where did you graduate and take your medical training?

A I took my medical training at the University of Tennessee, College of Medicine, Memphis.

Q And graduated when?

A 1950.

Q Do you limit your practice to any particular field of medicine?

A No, sir, I do not.

Q A general practitioner?

A Yes, sir.

Q Doctor Wedekind, are you familiar with the use of normal human plasma, irradiated, in connection with the treatment of diseases and in cases involving the loss of blood?

A Yes, sir.

Q Will you tell us whether or not such plasma is, or maybe is; or may contain the virus of serum hepatitis?

A It may, yes.

Q Doctor, I will ask you if in your opinion such a plasma which is so contaminated would be deemed to be adulterated?

(96) A Yes, sir.

Q And would the substance with which it is adulterated be deemed to be filthy?

A Speaking of the substance that was causing the hepatitis?

Q Yes, sir.

A Yes, sir.

MR. McAULEY: You may ask him.

CROSS EXAMINATION

By Mr. McAfee:

Q Doctor, have you ever seen any hepatitis virus?

A Pardon?

Q Have you ever inspected and actually seen a hepatitis virus?

A No, sir.

Q Isn't it true, Doctor, that it cannot be seen?

A Pardon?

Q Isn't it true that this cannot be seen?

A Most viruses, I understand, are able to be photographed with an electron microscope; for instance, the virus of poliomyelitis.

Q Have you ever isolated hepatitis virus?

A No, sir.

Q As a matter of fact, it can't be isolated, can it?

A I wouldn't know, sir.

(97) Q Do you know of any procedure or technique by which you could treat blood or blood plasma so as to destroy the virus?

A There are several procedures that are carried out.

Q Is there any procedure, Doctor, that will definitely destroy hepatitis virus beyond any question?

A Beyond any question?

Q Yes, sir.

A I don't know anthing in medicine that is 100 per cent.

Q I didn't get that answer.

A I said I don't know anything in medicine that is 100 per cent.

Q But isn't it true, Doctor Wedekind, that there is no way, no known method to destroy a virus in the blood, whole blood or blood plasma, without destroying the plasma itself?

A I do not know, sir.

Q You do not know. Do you use plasma in your practice, Doctor?

A At times, yes, sir.

Q You consider it beneficial in the practice of medicine?

A At times, yes, sir.

Q Doctor, what is the difference between homologous
(98) serum hepatitis and infectious hepatitis?

A Clinically, I would say the patient has a fever –

Q Yes, but what is the difference? There are two types of hepatitis. What is the difference between homologous serum hepatitis and infectious hepatitis?

A It is a difference of epidemiology only.

Q What do you mean by that?

A By that statement, I mean the difference lies in how the virus entered the body, whether by the gastro-intestinal tract, such as the drinking of water or by some injection that would be given as it would be in a serum hepatitis.

Q How many different ways can a serum hepatitis virus enter the body?

A If it were by mouth, of course, it could be in that manner. That is not the usual method. Usually, it is by injection.

Q By injection?

A Yes, sir.

Q Do you know some of the causes or the sources from which this serum hepatitis can be obtained?

A It has to come from someone who has had the disease.

Q Could a person contract that serum hepatitis virus from an unsterile needle which had been injected into another person's arm.

(99) A Before or after?

Q Before?

A If the other person had infectious hepatitis then that needle would be contaminated with this virus; yes, sir.

Q And a person could contract serum hepatitis virus from an unsterile needle in that fashion?

A Yes, sir.

Q Doctor, what is the incubation for serum hepatitis?

A It varies tremendously, sir.

Q It does?

A Yes, sir.

Q What are the periods?

A I think it is generally accepted as 60 or 160 days, 180 days.

Q What is the incubation period for infectious hepatitus?

A Generally accepted as roughly six weeks.

Q About six weeks?

A Yes, sir.

Q Doctor, if a person had not received a transfusion of blood plasma or whole plasma but in the course of 60 days he would have a case of hepatitis virus, what would you say caused that hepatitis?

A You say he had not had any serum —

Q Yes, sir.

(100) A — or plasma?

Q Yes, sir.

A What would I say had caused the hepatitis?

Q Yes, sir.

A It would be based principally on history. If there were a history of a needle injection —

Q I am assuming that he had no injection.

A No injection?

Q No, sir.

A That is different.

Q And within a course of 60 days he contracted a case of hepatitis, what would you say was the cause of that hepatitis?

MR. McAULEY: Sixty days from what, if the Court please?

Q (Continuing) Well, from the day he left the hospital. Assume that he was in the hospital but he had had

no transfusion of any kind, either of whole blood or plasma, 60 days after that time.

A You mean, in other words, a healthy person without any injection —

Q Yes, sir.

A Sixty days later developes clinically a hepatitis, viral hepatitis, what would I say caused it?

Q Yes, sir.

(101) A I would say it was a virus hepatitis.

Q Would you say an infectious hepatitis?

A If there were no history of injection, certainly.

Q Let's suppose he had an injection and 60 days later he developed hepatitis. What would you say caused that hepatitis?

A He had had a transfusion, now?

Q Yes.

A Or some plasma transfusion?

Q Yes.

A It is possible that that transfusion was contaminated with the virus.

Q But isn't it also possible that even though he had had a transfusion that he could have contracted the hepatitis through the mouth, through food, water, and it would still be infectious hepatitis, isn't that true?

A Yes, sir.

Q So, from a diagnostic point of view, there is no difference between the infectious hepatitis and the serum hepatitis, is there?

A I think we established that in the first question. Yes, sir.

Q Doctor, you say that in your opinion a hepatitis virus is a filthy substance?

A As the dictionary points out, an impure substance.

(102) yes.

Q Are you just taking the dictionary meaning of it or are you using your own meaning or your own definition?

A For what now?

Q Whether or not it is filthy.

A Whether the virus itself is filthy?

Q Yes.

A We are speaking of a virus or something containing a virus?

Q I am speaking of the virus.

A The virus is, itself, personally, is not filthy.

Q A virus itself is not filthy, is that correct?

A That is true. That is in my own opinion how I would describe it to another physician.

Q That is what I wanted, Doctor. Now, then, what about a virus in smallpox antitoxin, would you classify that as filthy?

A In smallpox antitoxin?

Q Yes.

A That is an attenuated virus.

Q Would that be filthy?

A Not as long as it was attenuated.

Q That is beneficial to people, isn't it, because it prevents smallpox?

A Yes, sir.

(103) Q Doctor, isn't it true that when a patient takes a transfusion there is always a calculated risk involved of contracting hepatitis?

A Yes, sir.

Q That is a calculated risk that is well known in the medical profession?

A You are speaking of a whole blood transfusion?

Q Or blood plasma.

A There is a calculated risk, yes, sir.

Q There is a calculated risk in both instances, isn't there, Doctor?

A The amount of risk is different, however, between a transfusion and a transfusion with pooled serum.

Q But it is a calculated risk in both instances, isn't it, Doctor?

A Yes, sir.

Q And that is well known among the medical profession?

A Yes, sir.

Q And when a doctor gives a transfusion of either whole blood or blood plasma, he gives it well knowing that calculated risk?

A Yes, sir. We don't use the transfusion on serum. We call that refusion. Transfusion is blood.

Q Now, Doctor, isn't it true that blood plasma can only be given or dispensed under a doctor's prescription?

(104) A Yes, sir.

Q You don't go out on the market and buy blood plasma like you would buy aspirin tablets and things like that?

A I don't know where the Red Cross obtains it but they get a whole lot of it.

Q But it is only given under a doctor's prescription?

A Yes, sir.

Q You say you have used plasma in your practice?

A Plasma?

Q Yes, sir.

A Not in my practice. I used it when I was in training.

Q What plasma did you use?

A I took my training at the Knoxville General Hospital. I couldn't tell you except we used the plasma. It was prepared there at the hospital.

Q Prepared there at the hospital?

A Yes, sir.

MR. McAFEE: I believe that is all.

REDIRECT EXAMINATION

By Mr. McAuley:

Q Doctor Wedekind, I believe you did state that plasma which was virus-free or contained no bacteria, would be considered a pure of unfilthy or proper plasma, is that correct?

(105) A Yes, sir.

Q If that same plasma does contain the hepatitis virus, I believe you stated that in your opinion it would be an impure virus?

A Yes, sir.

Q And therefore that was in that sense, you say, filthy?

A Yes, sir.

MR. McAULEY: That is all.

RECROSS EXAMINATION

By Mr. McAfee:

Q But you said in your opinion, in your opinion as a doctor, the hepatitis virus was not a filthy substance.

A In my description as a doctor of the word I wouldn't consider the word or organism itself as filthy, no, sir, just like I describe any other object.

Q Doctor, if you can't tell in advance whether or not blood contains a virus, then you can't tell whether the blood is pure or impure, can you?

A Speaking of whole blood now?

Q Yes, sir.

A No, sir.

Q You cannot?

A Now, let me qualify that statement, with respect to the virus as to contrast whether it is pure or impure.

(106) Q You could not tell?

A That is right.

By the Court:

Q I am not sure I understand you, or that the jury understands you. You stated that the virus itself was not filthy. Am I correct in that understanding?

A ~~Not as~~ a medical statement. I mean, if I were talking to someone I would not refer to a virus as being filthy. I would refer to it as being a foreign body. Filthy is a word I don't often use.

Q How is it considered in the medical profession or other scientific professions; how is the virus considered?

A I think it would be a matter of opinion, or word you use most frequently. If another person was describing it as filthy, I would not disagree with it at all.

Q Well, if it is not filthy in and of itself, do you say it is filthy when it is a part of blood?

A I would say so, yes, sir.

Q How do you make the distinction?

A Well, I admit that is a personality trait. In automobiles, some person might say one is attractive, and that is how it appears to that person, maybe not someone else.

THE COURT: Either side may ask him any further question that you desire.

(107) RECROSS EXAMINATION

By Mr. McAfee:

Q You do say that in the medical profession it would not be considered as filthy?

A By me?

Q By you.

A Yes, just speaking as generally some people might refer to it.

Q But you would not consider it filthy –

A Speaking of a virus itself or a substance containing it?

Q The virus itself.

A No.

Q And if you did not know, and you could not see the virus in the blood, impossible to see it, impossible to detect it, that it is in there, then you wouldn't say the blood was filthy, would you?

A You say it is impossible to see it. I agree with that, with the naked eye.

Q If it is impossible to see it, if it is impossible to isolate it, then you would not even consider the blood filthy, would you?

A Now let me go through this thinking process again. You are saying that since we can't do – well, let's put it a different way. If I had a bottle of blood and I (108) was told it was in there, I would say it is filthy, not fit for use.

Q They have admitted that we cannot detect the presence of a virus in blood. Now, if you can't detect it in the blood, you wouldn't say the blood was filthy; would you?

A If I don't know it is in there, no.

MR. McAFEE: That is what I wanted.

By the Court:

Q Can it be detected by microscope?

A An electron microscope, I am sure it can.

Q You are saying it cannot be detected by the human eye?

A That is right.

Q But it can by instruments?

A An electron microscope, yes sir. A virus is a filterable particle, through a filter.

MR. McAFEE: It has been conceded, the very reason that I agreed to take out the pamphlets. It has been conceded by the plaintiff that this virus cannot be detected under any circumstances and that is true.

There is no scientific, according to the authorities, the latest we have, there is no scientific method that it can be detected and no scientific method in which it can be eliminated.

(109) THE COURT: In view of that testimony, do you want to refer to the articles?

By Mr. McAfee:

Q Doctor Wedekind, you testified a few minutes ago that you did not know about whether or not it could be eliminated, didn't you?

A I can't remember specifically. To the best of my knowledge it can be eliminated by a period of prolonged storage.

Q You think it can?

A I think I recall reading that.

Q Where did you read that?

A I have forgotten now, sir. I read so many Medical Journals, I don't remember.

Q You don't even know where you read it?

A No. I am sure if I read it it was in one of three or four publications though.

Q Doctor, it was once thought it could be eliminated by radiation, wasn't it?

A Yes, sir.

Q But they found out that it couldn't?

A That's right.

Q And it hasn't been proven as a fact it can be elim-

inated by keeping it at room temperature for a long time, has it, Doctor?

(H8) A. I don't know.

Q You don't know?

A That's right.

MR. McAFEE: That is all.

REDIRECT EXAMINATION

By Mr. McAuley:

Q Maybe there is an analogy here, your Honor, of a virus. Let's get a few sizes up into the bacteria category. Say staphylo- whatever it is. That is a bug that can be seen under a microscope?

A Yes, sir.

Q Can't be seen by the naked eye?

A No, sir.

Q Suppose you got one of those bugs under a microscope and you see it nice, big, healthy, wiggling around, it is in that sense that you say that thing is not filthy in and of itself under a microscope; is that what I understood?

A In and of itself, it is just another living organ.

Q If you take a piece of sousemeat and sprinkled it liberally with the bugs, and I will ask you if you would consider that to be contaminated?

A It surely would.

Q And it is in that sense also with virus in the (J11) plasma?

A That is right.

MR. McAULEY: I think that is all.

THE COURT: Mr. McAfee, in view of the doctor's testimony, I suppose you desire to read the article?

MR. McAULEY: The matters referred to this morning or any part of them that you may desire while the doctor

is here, if you want to produce them to him, you may do so.

THE COURT: At the time the Court made the ruling this morning he did not know the turn that the case was going to take.

MR. McAULEY: I might state, Doctor Wedekind, we will concede that – and we certainly don't mean to take issue with you, but for the purpose of this lawsuit, that it cannot be detected. We concede that for the purpose of the lawsuit and in view of the doctor's position.

RECROSS-EXAMINATION

By Mr. McAfee:

Q Doctor Wedekind, do you know Roderick Murray, Assistant Chief, Laboratory of Biologics Control, United States Health Department?

A No, sir, I do not know the gentleman.

Q I want to read from an article prepared by him and see if you agree with it.

MR. McAULEY: For what purpose, may I inquire? (112) We will object to hearsay testimony.

MR. McAFEE: He is testifying in his opinion about keeping it at room temperature would destroy it. You said I could read this.

THE COURT: Go head. This is not substantive testimony, ladies and gentlemen of the jury. He is testing the witness by reading from certain pamphlets, testing the knowledge of this witness, and you will not consider what he reads as substantive testimony as proof of the things about which the article states or proof of the things in the article.

MR. McAULEY: Might the doctor, he says he can come back in an hour. He is needed in an operation. As

far as we are concerned he can read whatever he wants to read.

MR. McAFEE: If it is agreeable with him, just let me file all this material into evidence as exhibits.

MR. McAULEY: Purely as a matter of testing the doctor's credibility. All right, sir.

MR. McAFEE: I want to file this permit signed by Mrs. Kidd as Exhibit No. 3.

(EXHIBIT NO. 3 was filed.)

(EXHIBIT NO. 4, being Volume 31, May, 1955, No. 5, Bulletin of the New York Academy of Medicine, was filed.)

(113) (EXHIBIT NO. 5, a photostatic copy of an article published by the "Committee on Medicolegal Problems of the American Medical Association on the Subject Medicolegal Aspects of Blood Transfusions" was filed.)

(EXHIBIT NO. 6, a photostatic copy of an article on Jaundice Following Administration of Human Serum published in the Public Health Reports, volume 58, August 13, 1943, No. 33, was filed.)

(EXHIBIT NO. 7, a photostatic copy of an article on "Viral Hepatitis" taken from the Diseases of the Digestive System, Third Edition, 1955, was filed.)

THE WITNESS: Would you like for me to read that?

MR. McAULEY: No, only if Mr. McAfee desires you to read it.

MR. McAFEE: No.

(Witness excused.)

Doctor John H. Burkhart

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q. You are Doctor John H. Burkhart?

A Yes, sir.

Q. Where do you maintain your offices?

(114) A 3011 North Broadway, Knoxville.

Q Would you indicate your medical background and training?

A Well, I graduated from the University of Tennessee here at Knoxville, pre-med, 1941. I graduated from the University of Tennessee Medical College in Memphis in 1945, and one year internship at Knoxville General, two years in the medical offices in the army, one year residency in internal medicine at Knoxville General, and began private practice the 1st of July, 1949.

Q Are you a member of the Knoxville Academy of Medicine?

A Yes, sir.

Q And are you on any committee of the Academy?

A I am Chairman of the Public Service Committee of the Knoxville Academy of Medicine.

Q Doctor Burkhart, are you familiar with plasma, that is, normal human plasma, dry plasma, irradiated blood plasma?

A To some extent I am familiar with it, yes, sir.

Q And are you also familiar with the use of whole blood in transfusions?

A Yes, sir.

Q And, I believe, Doctor Wedekind indicated that in connection with the use of plasma the term "refusion" is (115) used?

A That is correct.

Q Doctor Burkhart, I would like to ask you this: Assume a bottle of plasma, restored plasma, here, which contains the virus of hepatitis, some hepatitis, I will ask you whether or not in your opinion that bottle of plasma containing that virus would or would not be considered to be impure, adulterated, filthy, for use in human beings?

A Yes, I would say it is.

MR. McAULEY: You may ask him.

CROSS EXAMINATION

By Mr. McAfee:

Q Doctor, what is hepatitis virus, can you describe it for us?

A Well, I am a practicing physician and not a bacteriologist or a biologist, and so I am not as familiar with it as I would be if I was that type of practitioner.

But a virus is a little organism which is capable of passing through a very fine filter. It is fine or finer than would be necessary to trap a bacteria, say, one or the other types of organisms that can invade human tissue, and it is capable of transmitting disease. In other words, of living as a parasite in human tissue. That is the definition as best I can give it now, of virus in general.

(116) The specific virus you asked about, the one that causes hepatitis, is simply the same type of virus which has an affinity for the liver and maintains its disease process there.

Q Are you telling this Court and this jury that in your opinion as a doctor that the virus itself is a filthy substance?

A I am not sure what the definition is of a filthy sub-

stance as pertains to this virus, but it is an impure substance and I would say it was a filthy substance; yes, sir.

Q Would you say the virus in a smallpox vaccination would be a filthy substance?

A No, sir.

Q It would not?

A No, sir.

Q Isn't it a substantially similar virus, that is, to the hepatitis virus?

A Well, yes, it is substantially the same, the way you are using it there. It would be the same in that sense. You would be using it in a pure culture of virus, and there is a difference in my way of thinking in something that contaminates another substance than something that is used in its pure state.

Q Doctor, you can't detect a virus in blood, can (117) you?

A No.

Q The hepatitis virus?

A No.

Q And there is no way to remove it from the blood, no treatment, practical treatment known among the medical profession by which it can be removed?

A Not to my knowledge, there is not.

Q Then, Doctor, how can you say something that you can't detect, something that you can't remove, could be filtered within the meaning of the medical profession as you use it?

A Because it is not a normal constituent of human blood.

Q Do you use plasma in your practice?

A Yes, sir.

Q Do you think it is a beneficial remedy to be used in the medical practice, is is not?

A Yes, sir.

Q But at the same time you are saying it is filthy if it contains a virus?

A If it contains a virus, yes, sir.

Q Doctor, the fact that plasma, or for that matter whole blood, may contain a hepatitis virus, that fact is well known among the medical profession isn't it?

(118) A Yes, sir.

Q Plasma was used with a great deal of success and benefit during World War II when they gave it to the soldier boys out on the battlefield.

A Yes, sir.

Q What is the advantage of using plasma over the whole blood, Doctor?

A Well, the first value is its availability. Whole blood has to be cross-matched for one thing and has to be compatible with the individual who is receiving it.

In other words, there are three types and then there are several sub-types which makes it necessary to match the patient's blood against the blood being given and see that they are compatible.

Plasma does not have to be cross-matched because there are no specific antigen and antibody reaction between plasma in one person and the pooled plasma, which is what dry human plasma is.

So the first advantage is in availability without having to be cross-matched and going through that process. Another advantage is that what you are actually trying to restore when you give plasma is circulating volume to build up pressure and bring the patient out of shock rather than overload them with red blood cells.

Q And as you say, rather than taking the time of (119) running all the tests and matching the blood for a whole

blood transfusion, you go ahead and give them blood plasma promptly?

A Yes, sir.

Q And, as a matter of fact, in that manner many thousands of lives have been saved that wouldn't have been, is that correct?

A Yes, sir.

Q It is generally considered among the medical profession that blood plasma is a fine and important medical remedy in use today?

A Yes, sir.

MR. McAFEE: That is all.

MR. McAULEY: Thank you very much, Doctor Burkhart.

(Witness excused.)

THE COURT: Mr. McAfee, do you want to have read that part of Doctor Gunn's testimony that I kept you from reading? You can do so because of the testimony of this doctor and the other, if you desire to do so.

In other words, I cut you off this morning because I did not know that anybody was going to make any point about a virus not being discovered by anybody.

MR. McAULEY: We still concede it can't be, your Honor.

(120) MR. McAFEE: In view of that, if the Court please, it seems to me they have a concession on this testimony here.

THE COURT: I think so, but I wanted you to know you were not being cut off from any testimony that you wanted to read before this case closed. I want to make that clear to you.

MR. McAFEE: That is all right. I don't think it is necessary in view of this concession.

THE COURT: Neither do I.

MR. McAULEY: We don't.

MR. McAFEE: In view that it can't be detected.

MR. McAULEY: We do not think that has any place in the lawsuit.

THE COURT: Call your next witness.

Mrs. Ann Douglass

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q You are Mrs. Anne Douglass?

A Yes, sir.

Q Mrs. Douglass, what is your occupation?

A I am supply room supervisor at St. Mary's (121) Hospital.

Q St. Mary's Hospital, supply room supervisor?

A Yes, sir.

Q How long have you been connected with St. Mary's Hospital?

A Well, I have been connected this last time for four years.

Q And, have you been there prior to that?

A Yes. I have been there for something around 20 years. Not all of the time together, but I suppose all my time put together would be about 11 or 12 years.

Q Mrs. Douglass, I will ask you this: Do your duties have to do with the cleansing of needles and equipment, operating equipment, knives and the like?

A Yes, sir.

Q Out there at the hospital?

A That's right.

Q That has to do with needles and the like other than those that come under Mr. Norris' domain, I believe?

A Well, the laboratory is a separate thing from the supply room. They run theirs themselves. My supply room covers the entire hospital and the treatment of patients after they leave surgery.

Q And the laboratory people do their own cleansing on their own equipment?

(122) A That's right.

Q But your function covers the entire hospital?

A Yes, sir.

Q Will you tell the Court and jury, Mrs. Douglass, just how it is that these needles that are used there are cleansed: what is the procedure?

A Well, of course needles are used only one time on a patient, and we have a great many needles, of course, that are used all during the day and night. And after they are used on the patient they are returned to the supply room and we put them to soak in a zephiran solution, which is for our own protection, and after they have soaked for a time, why we have a syringe that we first clean the top of them with a little power brush —

Q Something like a dentist drill?

A Black little brush with a motor on it, and take the top of a needle and hold it on the brush so as to cleanse the top, and after it is cleaned out, after that we take a syringe and run a green soap solution through the needle and put them in rinsing water and run the rinsing water though the needle, and then we put them in ether and we run the ether through them.

Q How do you do that?

A With a syringe. Squirt it through them, so that they are entirely open. And then we put them in a glass (123)

tube with a piece of cotton in the top and they are autoclaved at 20 pounds pressure, 240 degrees heat, for 20 to 25 minutes, and that is the end of that.

Q What is meant by autoclave?

A Well, an autoclave, if these people don't understand is, is a sterilizing unit that is put in all hospitals and it sterilizes everything that is used in the treatment of a patient.

Q Something like an oven or cook stove?

A Yes. It is like these pressure cookers that most people use but a little larger and a little bit more — has quite a bit more pressure.

Q Now, was that the procedure that was followed at St. Mary's Hospital as of 1954, March, 1954?

A Yes, sir. That procedure has been followed as long as I have been in charge of the supply room.

Q And the purpose of carrying the needles through these various procedures is to make them what?

A Well, of course, needles that are used from one patient to another, they would necessarily have gone through that process to be sure that they were completely sterile, and that is the procedure that is set up in all hospitals.

MR. McAULEY: You may ask her.

CROSS EXAMINATION

By Mr. Coburn:

(124) Q Mrs. Douglass, I believe your said these needles are used only once for each patient?

A Yes, sir.

Q What about the syringes?

A The syringes are only used one time, too.

Q They are?

A Yes, sir.

Q And then they are treated?

A That's right.

Q When you are giving a hypodermic, administering a hypodermic to a patient, of course you have the needle fastened on the end of the syringe?

A That's right.

Q Most of the hypodermic preparations are in a glass vial with a rubber cap on them, are they not?

A That's right.

Q And you pierce with the needle the rubber cap of that vial and withdraw the material and give it to the patient?

A That's right.

Q Those are multiple dose vials in a great many cases?

A Well, a great many – some of those are and some of them are not. Take Combiotic and Penicillin, and various other things of that kind, are only one dose to a patient. (125) They are put up as so many units in a dose. Like Penicillin, I think comes around 400,000 units, and then you put in 1cc of sterile water, of course, to mix that, and then you give that as a dose.

There are some medicines that are already measured that would contain maybe five ccs of something and you would only be giving that, just be given to one patient anyway.

Q But in some of these cases you do use a multiple dose container and in that case the material would be withdrawn from that container and used with different patients?

A Yes, but then you have a different syringe and a different needle each time.

Q Yes, I understand that. Have you ever heard of Doctor Roderick Murray who is the Assistant Chief of the Laboratory of Biologics Control of the National Institutes of Health?

A No. I don't think so.

Q Well, let me read to you from what is marked as Exhibit No. 4 in this case, in which Doctor Murray is describing the possible sources of danger and the possible sources of transmitting serum hepatitis through various hospital procedures.

Doctor Murray says:

"Another possible source of danger is the multiple (126) dose container, the contents or stopper of which may become contaminated if particular syringe procedures are not followed. Packages of biologics are now required to carry a warning statement in this respect."

Would you agree there is a risk in that area?

A Well, I don't believe I would be in a position to say. We follow orders and I don't think I would be competent to pass on that. I am sorry.

Q You would not dispute the existence of a risk there?

A I believe I will remain neutral and not say, as my opinion would not be of any benefit.

MR. COBURN: That is all.

MR. McAULEY: That is all.

(Witness excused.)

MR. McAULEY: Mrs. Kidd, will you take the stand?

THE COURT: Now, you are not going through the whole story with Mrs. Kidd about the condition of Mr. Kidd, are you?

MR. McAULEY: No, your Honor.

Mrs. Floyd E. Kidd

called as a witness by and on behalf of the plaintiff, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

(127) By Mr. McAuley:

Q You are Mrs. Floyd Kidd?

A Yes, sir.

Q Mrs. Kidd, did you accompany your husband to the hospital at the time of the leg injury?

A Yes, sir, I did.

Q How long was he in the hospital?

A I believe it was nine days.

Q After the first period of hospitalization with the one following the leg injury, I will ask you whether or not you were the one who looked after the hospital bill there?

A Yes, sir, I did.

Q Can you tell us what the charge was for the plasma?

A Well, the exact figure, I might not be exactly right, but it is three hundred and some dollars. I can't remember exactly.

Q I have in mind just the blood plasma.

A Thirty dollars.

Q Thirty dollars?

A Yes, sir.

THE COURT: Is that in addition to the $302.00?

MR. McAULEY: No. That bill is not even before the jury because that is the first period of hospitalization and before hepatitis was contracted.

You may ask her.

(128) MR. McAFEE: No questions.

By Mr. McAuley:

Q Do you remember signing the authorization which has been introduced as Exhibit No. 3, Mrs. Kidd?

A Yes, sir, that is my signature.

Q When was that done? Was that done upon admission or shortly thereafter?

A I beg your pardon?

Q When did they see you about admitting Mr. Kidd, was it there at the time?

A No, sir, after I taken Mr. Kidd into the emergency room and then when they started to take him up. They were taking him at that time around to surgery and I told him I was going on and change my clothes, that I would be back, then I went home and changed my clothes and came back and went to the admitting office and that is when I signed it.

Q And signed him in?

A Yes, sir.

Q Including this document here?

A Yes, sir.

MR. McAULEY: That is all.

MR. McAFEE: No questions.

(Witness excused.)

MR. McAULEY: That is the plaintiff's case, your Honor.

(129) MR. McAFEE: I would like for the jury to step out.

THE COURT: All right. Let the jury step out.

(Whereupon, the following proceedings were had in the absence of the jury, to-wit:)

MR. McAFEE: If your Honor please, the defendant moves the Court to direct the jury to return a verdict in favor of the defendant upon the following grounds:

No. 1. There is no proof that the plasma given to the plaintiff contained a jaundice virus. I want to amend that by saying the hepatitis virus.

No. 2. There is no proof a virus in the plasma was the cause of the plaintiff's hepatitis.

No. 3. There is no proof the plasma received by the plaintiff Kidd was adulterated within the meaning of the Tennessee Food, Drug and Cosmetic Act.

No. 4. Because the proof shows that in all cases of transfusions of plasma there is a calculated risk involved that the plasma may contain hepatitis and could cause the recipient to develop jaundice or hepatitis, and this risk was known to and assumed by the plaintiff.

No. 5. Because the undisputed evidence shows that blood plasma is used only on orders of a doctor and the action of the plaintiff's doctor in ordering and giving the transfusion of plasma to the plaintiff constituted an independent intervening cause breaking the causal connection (130) between the defendant's act and the ultimate injury sustained by the plaintiff.

And, finally, because there was no proof introduced upon which a verdict for the plaintiff can be sustained.

(Whereupon, counsel presented oral argument on the motion for a directed verdict.)

THE COURT: I will hear the proof of the defendant. Overrule the motion at this time. It may be renewed. Call the jury.

(Whereupon, the following proceedings were had in the presence of the jury, to-wit:)

Richard C. Sexton, Jr.,

called as a witness by and on behalf of the defendant, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAfee:

Q Doctor Sexton, please state your full name, your age and your occupation?

A Richard C. Sexton, Jr.; age 37; physician.

Q Where did you get your medical training, Doctor?

A University of Tennessee.

Q Have you had any special training in any particular line?

(131) A Yes. I specialize in the field of internal medicine.

Q How long have you been practicing medicine?

A Approximately three and a half years here in Knoxville.

Q Where are you originally from?

A From East Tennessee.

Q Union County?

A Yes, sir.

Q Doctor, would you please describe for us just what a virus is, a hepatitis virus, if you can, please, sir?

A The term virus is applied to an infectious agent which is referred as being ultra-microscopic.

THE COURT: I cannot hear you distinctly. Will you talk louder, please?

THE WITNESS: The term virus is used in describing an infectious agent which is said to be ultra-microscopic, that is, it cannot be seen by the microscope, by the aid of the microscope, and that particular type of virus produces the clinical disease which we refer to as viral hepatitis.

Q Would you consider a virus which you have just described as a filthy substance or an adulterated substance?

A Well, I think that depends upon one's definition of filthy and would depend upon the context in which the virus was found to exist.

(132) Q Let me ask you this question. If a virus is found in blood, in a donor's blood, would you say that under the conception in the medical profession would you consider that as a filthy substance?

A I would prefer to use the term contaminated. I think in a medical sense I would not regard the plasma which contains a virus as being filthy except perhaps in a retrospective sense.

Q Explain that, Doctor.

A By retrospective, I mean it may be apparent three or four months after the infusion of plasma is given, that it contained a virus, but it would not be apparent by any available technique at the time it was given.

Q That it was a filthy substance?

A Yes, sir.

Q You regard plasma as a beneficial product in the practice of medicine?

A Yes, sir.

Q Do you use it in your practice?

A Yes.

Q Let me ask you this: Isn't it possible for blood plasma to be given to one person and that person may contract hepatitis and the same plasma from the same batch be given to another person and the other person not contract hepatitis?

(133) A Yes.

Q Why is that, Doctor?

A I don't believe that the exact reason for that is

known. Presumably it is related to some intrinsic defense mechanism of the person who does not become infected.

Q In other words, one person might have some antibodies that build up an immunity to the virus and others might not, is that correct?

A Yes, that is probably one mechanism.

Q Can you think of others?

A I think there are probably others of which we are not aware of in the present state of our knowledge.

Q Do you know of any method in which a virus can be destroyed or its harmful effects done away with in blood or blood plasma?

A To my knowledge there is no method by which blood can be completely rid of the virus of hepatitis.

Q Isn't it a well known fact among the medical profession there is always a calculated risk in giving transfusions, even of whole blood and blood plasma, that the recipient may contract hepatitis?

A Yes, sir.

MR. McAULEY: Objected to as leading.

THE COURT: Overruled.

By Mr. McAfee:

(134) Q Is that true?

A Yes, sir.

Q And that calculated risk is recognized among the medical profession in this country?

A Yes, sir.

Q Is there a difference between the virus of infectious hepatitis and the virus of serum homologous?

A There is thought to be on what we refer to as an epidemiology and hemologic basis. However, all attempts to grow the virus or to reproduce the disease in experimental animals have been unsuccessful. So it is true that two distinct viruses do exist, however, absolute proof of

that fact is lacking. That differentiation is based upon what we refer to as clinical grounds.

Q How many different ways can a person contract hepatitis?

A Do you refer to the serum hepatitis?

Q Serum hepatitis.

A Well, I have never stopped to enumerate the different methods, but we know that it is conceivable that a needle puncture or instrument puncture of the skin under any circumstances might conceivably convey the virus hepatitis to the individual, or it can be acquired as a result of the breakdown of blood products, such as thrombine in the blood.

Syringe hepatitis has been described as simply (135) indicating that the disease was acquired as a result of a needle puncture or as a result of contamination of the syringe which was used in administering these medications.

Q People that are dope addicts, where they puncture the skin, is that a source of it?

A Yes, cases have been described in dope addicts.

Q What about tattooing?

A Cases have been described following tattooing.

Q Doctor, as you stated that it is impossible to detect the difference between an infectious virus and a homologous serum hepatitus virus, how can you diagnose whether it is an infectious hepatitis or homologous serum hepatitis?

A First of all, I would like to indicate that in my opinion one cannot differentiate it to an absolute certainty unless one can be absolutely sure that the patient has not been exposed by any of the aforementioned techniques to the virus of serum hepatitis; if not, then there might be question as to the exactness of the diagnosis.

As we previously indicated, in most instances the diagnosis, the clinical diagnosis, is based upon the appearance of

the patient, the nature of the onset, whether or not the onset is instantaneous or explosive; whether or not the onset is featured by extreme temperature elevation, and whether or not the patient has received blood or blood (136) products which might have contained the virus of serum hepatitis, and, lastly, the period of time that elapsed between known exposure to a patient or person who may have acquired the form of disease and the length of time which might elapse between giving the plasma or blood or some blood product.

Q Suppose or assume that a person has been given a transfusion of plasma in the hospital and within the incubation period of the time of, say, 60 to 120 days, he developed a hepatitis. How would you diagnose that hepatitis?

A The patient has received an infusion of plasma?

Q Yes, sir.

A Within the incubation period of serum hepatitis?

Q Yes, sir.

A Well, I would anticipate that the clinical onset of the disease in such patient would be insidious. The patient would be very vaguely ill with a poor appetite, general ill feeling, perhaps with little or no temperature elevation, for several days prior to the time at which the disease reaches its recognizable clinical state. Often the patient is so ill for several days before jaundice makes its appearance and, indeed, the patient may not become jaundiced.

Q How would you know that patient had not contracted infectious hepatitis, say, within 21 days of that time?

A If such a patient became acutely and explosively ill one could not differentiate the two.

(137) MR. McAFEE: I believe you may ask him.

CROSS EXAMINATION

By Mr. McAuley:

Q Doctor, is there a device known as an electron microscope?

A Yes, sir.

Q Can a virus be photographed with that machine?

A Yes, I believe so.

Q Possibly even the hepatitis virus?

A Possibly. I am not aware of a specific answer to that.

Q Mr. McAfee asked you about plasma containing the virus of serum hepatitis and whether or not in your opinion that would be considered a filthy substance.

I believe you indicated that would have to be arrived at retrospectively. By that do you mean after the fact?

A By retrospective, I simply mean that one could not take, say, a pint of plasma and by any technique of which I am aware; determine that it contains the virus.

Q Yes, sir.

A The only way it could be done would be to give it to the patient, give it to a human volunteer, and await the elapse of the incubation period for serum hepatitis.

Q And assuming that has taken place and some 60 to 120 more days have passed and the disease does develop, you (138) still have a little bit of that same bottle, then retrospectively that would be a filthy substance, would it not?

A I think I prefer to think of a filthy substance in a medical sense, and by that I would prefer to refer to a substance that is being utilized in medicine as being contaminated or not contaminated.

Q Yes, sir. Well, if you heard some layman refer to it,

says that is a filthy bottle of blood, you would know what he was talking about especially if he is the victim?

A Well, I think perhaps you have some conception; however, I would prefer to think of it in a medical sense.

Q Now, you indicated, I believe, that assuming a batch of plasma which, we will say is retrospectively filthy or impure, and you say that one person may come down with the disease whereas another person given an infusion from that same batch might not come down, is that correct?

A Yes, sir.

Q Now, if the person who came down with the disease did not change his diet or change the source of his water slightly, and that sort of thing, and he did develop it within the incubation period of serum hepatitis virus, which would be 60 or more days, then presumably he would have hepatits from that plasma, would he not?

A Assuming that he had not been given any other blood products, I think there would be a good statistical (139) probability it was serum hepatitis.

Q And the mere fact that somebody else might not come down with the disease doesn't keep it from being equally a fact that this individual did come down as a result of this very virus, isn't that true?

A I think that is true. Yes, sir.

Q And you say the typical symptoms would be lethargy, vague illness, poor appetite and the like for a period of as much as a week before he would actually be hospitalized or treated?

A You are speaking of the serum type?

Q Serum type.

A Yes. I think what we might refer to as prodromal symptoms would vary with the individual.

Q Well, two weeks would be a reasonable period of time?

A Yes.

MR. McAULEY: I believe that is all.

REDIRECT EXAMINATION

By Mr. McAfee:

Q Doctor, is it possible for a person to be a carrier of a virus?

A Yes. It seems established that there is such a thing as what we call an asymptomatic carrier. That is, a patient harbors the virus in the blood and is not ill.

(140) Q Could that be caused from tattooing on his arm? Could he become a carrier or maybe contract it in that manner?

A That is conceivable. Presumably, the virus, such as that which is in plasma pools, comes from people who did not have the disease, who have not had recognizable virus hepatitis in the immediate past.

Q You were talking about photographing the virus and he mentioned the electron miscroscope. You couldn't photograph something unless you could isolate it, and catch it and –

A Of course, visualizing the virus is not synonymous with isolating it insofar as a culture or propagating it or growing it goes.

I think the interesting fact about this disease is that they have not been able to reproduce it in experimental animals or to grow the virus on any culture media.

Q Now, blood plasma is not sold open to the public, it is sold and dispensed only upon a doctor's prescription?

A It is given as a result of a doctor's request; yes.

Q And in each instance as to whether or not the plasma is to be administered to a patient, that decision must be left to the doctor?

A Yes.

MR. McAFEE: All right.

(141) RECROSS EXAMINATION

By Mr. McAuley:

Q Doctor, how does the virus affect the liver, or the architecture of the liver so to speak?

A Well, I am not sure that there is an absolute so-called structure pattern, however, it produces evidences of inflammation. It produces what we call round cell infiltration, which is one of those evidences of inflammation, and in some patients of course in which the disease is more serious there may be actual death of small areas of liver tissue.

Q Is it recognized that there are three stages, generally speaking, in the disease?

A Are you speaking from a tissue point of view or from a clinical point of view?

Q Well, does the word symptomology help you – it doesn't me?

A We define the disease into what we call the preatonic, which is the phase before the development of jaundice, the atonic phase which is the phase during which jaundice is found, and the postatonic phase which is the phase of convalescense after the disappearance of jaundice.

Q Then, is it not true there is a terminal stage where the patient dies?

A A certain percentage of patients do die. Of course, (142) those are patients in whom the disease is somewhat

— it is progressive. The patient becomes comatose and dies.

Q May not the disease also be chronic in that the patient may be symptom-free for a period of time and then have relapses and recurrences of the same initial symptoms?

A There is an entity which we describe as subacute hepatitis. It is recognizable by appropriate tests of liver function. I would say chronic hepatitis is an ill-defined clinical syndrome.

Q There is no definite pattern by which the thing is apt to or apt not to reappear. It is somewhat the same as it was initially, it may be violent or not?

A If you have recurrent nepatitis, yes. I would say that the recurrent might be less severe or more severe or it might be difficult to be sure —

Q Is it true that after you once suffer from hepatitis, a good solid jolt of it, that might reoccur in that individual at any time throughout his life?

A I would say that it is conceivable, but I would say that after one or two years that a recurrence would be quite unlikely statistically.

Q Suppose there was a recurrence 16 months after the initial onset, would that render a further recurrence more likely in your opinion?

A Perhaps. I think that our statistics on that are (143) perhaps not adequate to give you a definite answer on that.

Q But as it is true of many other things it is possible?

A Yes.

MR. McAULEY: I believe that is all.

MR. McAFEE: That is all.

(Witness excused.)

E. Charles Sienknecht, M. D.,

called as a witness by and on behalf of the defendant, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. McAfee:

Q Doctor Sienknecht, please give us your full name, your age, and your present occupation.

A Elmer Charles Sienknecht, Jr., 38, physician.

Q What is your educational background, Doctor?

A Graduate of the University of Tennessee, University of Tennessee College of Medicine, and a diplomate of the American Board of Internal Medicine.

Q Do you hold any position with the local Medical Academy?

A I am president this year.

Q President of the Knoxville Medical Academy this year?

(144) A Yes, sir.

Q Doctor, are you familiar with the use of blood plasma?

A Yes, sir.

Q How long have you been practicing medicine?

A Fifteen years.

Q Do you use blood plasma in your practice?

A Yes, sir, when necessary.

Q You consider it a beneficial remedy to be used in the medical profession?

A In the proper case, yes, sir.

Q Doctor Sienknecht, do you know of any method where the hepatitis virus can be destroyed in whole blood or blood plasma?

A No, sir, I do not.

Q There is none known to the medical society at this time?

A Not without endangering the plasma. You mean, and still keep everything else as it should be?

Q And still keep the plasma.

A There is none that I know of.

Q There is no known method at the present time where this virus can be destroyed without destroying the plasma?

A Not absolutely.

Q Can you describe for us just what this hepatitis (145) virus is that exists?

A It is hard to describe a virus, but a virus is a little organism smaller than bacterium which produce or transmit disease, and can produce, I should say.

Q Would you say a hepatitis virus is a filthy substance?

A No, sir, I would not.

Q Why wouldn't you say it is a filthy substance, Doctor?

A I think it depends on your definition of filthy.

Q In your terminology and in the terms of medicine, can you say it?

A In medicine we use the term "contaminated" instead of filthy. It is a little more accurate. I wouldn't say that a virus is a substance of contamination unless it has been added to something already present.

Q Is a hepatitis virus a natural product of the blood?

A No, sir, but it may exist without any symptoms whatever or any disease producing conclusions.

Q A person could have a virus in his blood and never know it?

A Yes.

Q Doctor, is it possible – let me ask you this question first.

(146) Is there a calculated risk involved when you give a transfusion of whole blood or blood plasma?

A Yes, sir.

Q What is that risk, Doctor?

A The risk of homologous serum jaundice and any reaction that might occur. It is not the only one.

Q That is a calculated risk that every doctor takes, or every patient takes that receives the blood when he takes a transfusion?

A Yes, sir.

Q Doctor, is it possible for a transfusion to be given to one person and that person contract hepatitis, and the same plasma given to some other person and the other person not contract the hepatitis?

A Yes, sir, I would say it is possible.

Q Why would that be possible, Doctor?

A It would depend upon the ability of the recipient to fight off the infection by that virus. The same dose of virus in every person does not produce the same disease.

Q Some persons may have an antibody built up against it?

A Yes, sir. Their resistance to this may be such they would not get the disease.

Q Doctor, plasma is only distributed to patients upon a doctor's prescription, isn't that correct?

(147) A To the best of my knowledge, yes, sir.

MR. McAFEE: All right.

CROSS EXAMINATION

By Mr. McAuley:

Q Doctor, you say there is no way to destroy the hepatitis virus?

A I believe I said absolutely, not absolutely destroy it.

Q Now, could you tell us what is the incidence of serum hepatitis virus in the average population here in

the United States? Would one in 200 strike you as a fair figure?

A I would not testify to that figure but sounds approximately right. I am really not exactly sure of that.

Q Now, the risk of a person contracting the disease is greater with plasma than it is with whole blood, isn't it?

A Yes, sir.

Q If 50 donors pool their blood into one pool and from that pool injections or infusions are made after it has been reduced to the powder form and then later restored as true plasma, would the risk then not be 30 times or 25 times greater statistically, assuming that the one to 200 figure is correct; would not the risk be about 25 times greater from taking the plasma from this pool of 50 than in (148) a single donor case?

A It is much more common, sir. I couldn't quote the figures. I am not that much a mathematician.

Q If you use it from a hundred donors instead of fifty you again double the risk?

A The greater the pool the greater the possibility.

Q The greater the pool the greater the possibility of that?

A Yes, sir.

Q Do you have any knowledge concerning the cost of processing plasma?

A No, sir.

Q Would it be more economical to use a large group than a small group, in your opinion, considering the frequency of cleaning the equipment and that sort of thing?

A I have no idea. That would be entirely with the facilities at hand, whether you could deal with a large amount or a small amount.

Q It would be your guess that it would be more economical to use the large group than the small group?

A I think it would depend on the facilities present. Here in Knoxville you couldn't get a large pool, there are not facilities for it, and that would depend on other circumstances.

Q I believe although it is possible for one person (149) to contract a disease from the given pool yet another person might not contract it, is that correct?

A That is correct.

Q But in any event, barring any other source, it would nevertheless be true that the one who did contract it got it from that place, would it not?

A If there were no other possible source of infection; yes, sir.

Q It would be unquestionably from that plasma even though some other person might not get it?

A No, sir, that is not true. I think it has been stated that every diagnosis of homologous serum jaundice is made on circumstantial evidence. There is no way you can be sure it is from the plasma.

Q Based on the incubation period largely, than history?

A Yes, sir.

Q And there is quite a difference between the incubation period of the viruses.

A It is so thought.

Q That is accepted in the medical profession, is it not?

A Not as a proven truth, because these viruses have never been studied to that extent, I believe.

Q But the effect of those viruses have been studied?

(150) A Yes, sir, and that is the way they base it.

Q That is the way you go at it?

A Yes, sir.

Q And about 42 to 28 days be about right for the incubation period of infectious hepatitis?

A I believe an average of three weeks.

Q With respect to serum hepatitis, it would be a longer period, say 60 to 120 days?

A I believe the term three months is the average they used.

Q I believe you stated, Doctor, that rather than use the word filthy you would use the word contaminated, is that correct?

A I said that we usually use that term in medicine rather than the word filthy.

Q But the term filthy might very well be used in the ordinary lay sense which would have the same kind of connotation of your use of the word contamination with respect to the virus?

A Well, that would be — of course, it wouldn't be particularly a medical term.

Q But it would be an ordinary term.

A It could be used instead of.

Q The unscientific term?

A Yes.

(151) Q Are you familiar with the magazine, am I right on this, "Surgery for Gynecology and Obstetrics," is there such a publication?

A Yes, sir.

Q Do you from time to time see that magazine?

A In my specialty I don't read that particular magazine.

Q Did you ever hear of a Doctor J. Garrott Allen?

A I have read his works in other magazines.

Q Have you read his work recently as to liquid plasma?

A I have read articles by him on that subject; yes, sir.

Q And he advocated that plasma be permitted to stand at room temperature for six months.

MR. McAFEE I want to object. This is getting into

an entirely different subject, the field of liquid plasma, it has nothing to do with this question.

THE COURT: That testimony is not competent to prove the truth of the statement in the pamphlet from which Mr. McAuley is reading, but it may be used to test the witness' testimony — to test the knowledge of the witness on the subject under consideration and for that purpose only, ladies and gentlemen of the jury.

By Mr. McAuley:

(152) Q May I read you this, Doctor?

"Pooled liquid plasma stored at room temperature of 72 — 95 degrees Fahrenheit six months or longer, is fully as safe as whole blood insofar as transmission of serum hepatitis is concerned."

Have you seen that appear as a statement of the Board of Regents of the American College of Surgeons?

A No, sir, but I have no connection with the American College of Surgeons. I wouldn't have had any opportunity.

Q You have read of the six months' pooled plasma proposition?

A I have heard of this doctor's work, yes, sir.

MR. McAULEY: The only reason I mention that, it was mentioned earlier by some of the witnesses that there was such a thing as safe plasma, and that was the only reason I mentioned it.

We would like to file this article as Exhibit No. 8.

(EXHIBIT NO. 8 was filed.)

REDIRECT EXAMINATION

By Mr. McAfee:

Q Did I understand you to say that every diagnosis of hepatitis must be based on circumstantial evidence?

A Every diagnosis of homologous serum jaundice is (153) made on circumstantial evidence; not infectious hepatitis.

Q There is no absolute test which you can make to diagnose homologous serum hepatitis?

A No, sir.

Q Now, Doctor Sienknecht, what are the advantages of blood plasma over whole blood?

A Its easy availability is the only one I know.

Q In giving transfusions of whole blood there is quite a bit of testing and time involved?

A Yes, sir.

Q And in those cases where the patient must have blood and have it immediately, that is the cases where the plasma comes in?

A Yes, sir.

Q They used it extensively on the battlefields in the war?

A Yes, sir.

MR. McAFEE: That is all.

MR. McAULEY: That is all.

(Witness excused.)

Robert B. Wood, M. D.,

called as a witness by and on behalf of the defendant, after having been first duly sworn, was examined and testified as follows:

(154) DIRECT EXAMINATION

By Mr. McAfee:

Q Doctor Wood, would you please state your full name and your age, sir.

A Robert B. Wood. What was the other question?

Q What is your age?

A Fifty-nine.

Q What is your present occupation, Doctor?

A Physician.

Q How long have you been a physician?

A Graduated in 1921.

Q Give us a little background of your education, Doctor.

A I studied at the University of Tennessee for four years, Vanderbilt four, had intern training at New York, and general practice for 10 years, limiting my work in the internal medicine field for the last twenty-odd years.

Q How long have you been practicing here in Knoxville?

A Since 1923.

Q Since 1923?

A Yes, sir.

Q Doctor, are you familiar with the use of blood plasma?

A Yes. I have used it.

Q Would you consider blood plasma beneficial to (155) the practice of medicine today?

A Yes, it is quite helpful in certain types, certain circumstances.

Q Are you also familiar with the hepatitis virus, Doctor?

A Yes. I have seen several cases of hepatitis of various types. The literature has been quite plentiful on hepatitis since World War II.

Q Could you describe for us just what virus, what that virus consists of, what it is?

A Virus is a classification of bacteria. It is a microscopic bacterium, that is, it is not visible to the eye; it is not visible under the normal ordinary microscope.

It is a very small organism and will pass through filters which are used for taking out ordinary bacteria.

Q Is there any method known to medical science today to destroy that virus without destroying the plasma?

A No, not with certainty; no, sir.

Q Doctor, the virus that you have just described, would you call that a filthy substance?

A No. Medically, I wouldn't do so. I wouldn't speak of it in that term.

Q Doctor, let me ask you this: Is it possible for one person to take a transfusion of blood plasma and contract hepatitis virus or hepatitis from it, and another person to (156) take a transfusion of the same plasma and not contract the hepatitis?

A Yes.

Q Why is that true, Doctor?

A Not over 50 per cent of the people injected with the material that is known to contain the virus will develop it. That is because presumably that some individuals have an immunity against the organism.

Q Others don't?

A Others don't, that is right.

Q Is that virus a natural condition in some people's blood?

A I wouldn't say it was exactly a natural thing but many people carry it without knowing it and there is no way of discovering that they have it. Because, for instance, in taking blood from individuals there is no way of determining who may have the virus in them because you can't even inject and produce that condition in animals. Man is the only animal that has that particular disease. You can't transmit it to birds or other types of animals.

MR. McAFEE: Thank you very much, Doctor.

CROSS EXAMINATION

By Mr. McAuley:

Q Doctor, now the one who is not immune that Mr McAfee speaks of the one who is not immune from that (157) disease, nevertheless remains hepatitis-free until that bug is introduced in his system, doesn't he?

A Yes. He can't develop hepatitis without in some way having the organism to enter into his system.

Q Introduced into his system?

A Yes, sir.

MR. McAULEY: That is all.

REDIRECT EXAMINATION

By Mr. McAfee:

Q He can, though, get that germ from food?

A Oh, yes. There are many other ways of picking up the infection. The oral method as well as – it can be given in anything that enters into the body, that pierces the body, hypodermic needles, or various types of infection, and things of that type.

Q What is the incubation period for infectious hepatitis, Doctor Wood?

A For infectious hepatitis it is a variable but is considered to be up to a matter of a few weeks.

There are different types of virus infections that can produce hepatitis, the ordinary infectious hepatitis. In the matter of what is known as homologous serum hepatitis it is longer, thought to be longer, and may go on up for several months.

Q Now, will you say the incubation period for (158) infectious hepatitis is a short time –

A It is considered short, but I am sure there are overlapping incidents.

Q What do you mean, Doctor, a short time from when?

A From the time that he is exposed or from the time when that enters into his body.

Q And how does a man contract infectious hepatitis?

A Oh. Well, it can happen – it can be introduced simply by coming in contact with an individual that has it, where he has contaminated material that enters into his body through the oral method.

Q The mouth?

A Through the mouth, yes, and then there have been epidemics of jaundice reported from the use of syringes.

I read recently of one that happened in a group of diabetic individuals, thought to have been produced by contamination of a syringe.

The virus is very hard to destroy and there is no known way by which you can definitely be certain that he has gotten rid of it.

MR. McAFEE: All right.

RECROSS EXAMINATION

By Mr. McAuley:

Q Plasma containing the serum hepatitis virus would not, in your opinion, be considered to be pure and wholesome, (159) would it?

A No. I don't think you would use that terminology in regard to it, no.

Q Could it, in giving it, say, the ordinary, unscientific, ordinary meaning and not confining it to the scientific or medical definition, could it be referred to as filthy by the layman?

A By filthy do you mean contaminated?

Q I mean it contains the virus of serum hepatitis.

A Well, I don't think that one would dispute the fact that it may contain the virus of hepatitis.

Q And if it does contain it it would, in the lay sense at least, be filthy, would it not?

A I don't like that word "filthy." I think that implies a foreign substance that normally you would think of having been introduced in it some time between the time the blood was drawn from the fellow who had it and the giving of it.

It was in that individual's blood who gave the blood to make the plasma. He did not know it and it was not bothering him. He was carrying it and he was perfectly healthy to all intents and purposes, and there is no way whereby anyone would know when they drew that blood it was in there. So when you speak about it having been contaminated or filthy, you are thinking about it in terms of something (160) that is retrospective and not something you can visualize at the time by looking at the serum or by examining the individual who had the difficulty.

Q And so those terms would have to be applied retrospectively after it has been established that it did contain the virus?

A Yes, sir, the retrospective terminology.

MR. McAULEY: That is all.

MR. McAFEE: That is all, Dr. Wood.

(Witness excused.)

THE COURT: Take a recess, gentlemen.

(A short recess was had.)

THE COURT: Call the next witness.

Eugene S. Barclay,

called as a witness by and on behalf of the defendant, after having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. Coburn:

Q Mr. Barclay, will you please give us your full name and your age and your residence address?

A Eugene S. Barclay, 44-36 Ridenour Drive, Newtown Square, Pennsylvania.

Q And your age?

A Forty-four.

(161) Q I wasn't sure that was your age or your address. By whom are you employed at the present time?

A Sharp & Dohme Division, Merck & Company, Incorporated.

Q And in what capacity?

A Director of Biological Production.

Q And for what period of time have you held that position?

A A little more than three years.

Q And prior to that time, what position did you hold, immediately prior to that time?

A Assistant to the Director for 14 years.

MR. COBURN: If the Court please, I would like to file as No. 9 the photostatic copy with a stipulation as to its correctness of the license issued to the Sharp & Dohme Division, Merck & Company, Incorporated, by the Department of Health, Education and Welfare, under the Federal Virus Serum Antitoxin Act for the production of, among other products, normal human plasma.

MR. McAULEY: No objections.

(EXHIBIT NO. 9 was filed.)

By Mr. Coburn:

Q Mr. Barclay, what steps, if any, do you have to go through in order to secure a license of that type?

A In order to secure a license from the National (162) Institutes of Health for any product, it is necessary to —

Q Excuse me. License from the Department of Health, Education and Welfare, and the National Institutes of Health is a part of that?

THE COURT: Read that answer, please.

(The answer was read.)

A (Continuing) — it is necessary to petition the National Institutes of Health, describing among other things the name of the company, the address of the company, the product for which you wish a license, a complete processing description of the product, the tests you put it through, the expiration date, that the people who are doing the particular job are competent — I think that, in a general way, covers it.

By Mr. Coburn:

Q Mr. Barclay, I show you a document which is entitled "Federal Security Agency, Public Health Service, National Institutes of Health, Bethesda, Maryland, Minimum Requirements, Normal Human Plasma, 9th Revision, May 15, 1952," and ask you if you can tell me what this document is?

A These are the rules and regulations for the minimum requirements as required by the National Institutes of Health in the production of this product. It must conform to all the stipulations set forth in this document.

MR. COBURN: May I file this also as Exhibit No. (163) 10.

(EXHIBIT NO. 10 was filed.)

By Mr. Coburn:

Q Mr. Barclay, in fact in the production of normal human plasma by the Sharp & Dohme Division under this license from the Federal government, are all the requirements that are set forth in that document, Exhibit No. 10, faithfully followed?

A Yes, sir.

Q I would like to call your attention particularly to one of the amendments, Amendment No. 3, of this document, and ask you if you would read Amendment No. 3 into the record.

A "Minimum Requirements: Normal Human Plasma (9th Revision) Amendment No. 3.

"Effective March 2, 1953, Section 9.2 is hereby amended by the addition, following Section 9.23, of Section 9.24 reading as follows:

"Section 9.24 Either the label or circular for normal human plasma must carry a warning statement to the effect that despite careful donor selection and ultraviolet irradiation, the plasma may contain the virus of homologous serum hepatitis.

"It is desired that the foregoing be put into effect as soon as practicable in advance of the effective (164) date. However, packages now finished, or finished before the effective date may be issued without the statement required by this amendment."

Q And that is a requirement of the Federal agency controlling the manufacture of this product?

A That is correct.

Q I show you, Mr. Barclay, Exhibit No. 1 annexed to the deposition of Doctor Gunn in this proceeding, and ask you if that pamphlet contains a statement on the risk of serum hepatitis in conformity with the requirements of the National Institutes of Health?

A Yes, sir, it must, because we must submit all of our literature to the National Institutes of Health for approval before use. I know that it does.

Q And that pamphlet actually accompanies the plasma as part of the plasma when it is shipped and sold?

A Yes, sir.

Q Does the National Institutes of Health employ any inspectors in aid of the enforcement of this act under which you hold this license?

A Yes, sir, that is part of the biologics law.

Q And the Sharp & Dohme Division plant where normal human plasma is produced has been inspected from time to time by these government inspectors?

A Routinely, yes, sir.

(165) Q Do you have complaints from them as to the procedure under which you operate?

A No, sir.

MR. McAULEY: That would be hearsay.

THE COURT: Well, I will let him answer.

By Mr. Coburn:

Q I didn't catch the answer?

A No, sir. We have no complaints.

MR. COBURN: Thank you, Mr. Barclay.

CROSS EXAMINATION

By Mr. McAuley:

Q Mr. Barclay, Merck Company, Incorporated, is not a charitable institution, is it?

A No, sir.

Q It is a rather large pharmaceutical house?

A Yes, sir.

Q It is in business to make money?

A That's right.

Q And succeeds?

A I assume so.

Q Now, you referred to your license. I believe that is issued by some Federal agency?

A That's right.

Q I was wondering if in that license which is issued by this Federal agency, there is any provision in there (166) which excuses compliance with the Tennessee Food, Drug & Cosmetic Act?

A No, sir, not that I know of.

MR. McAULEY: That is all.

REDIRECT EXAMINATION

By Mr. Coburn:

Q How long has Sharp & Dohme as the predecessor of Sharp & Dohme Division, Merck & Company, been in the pharmaceutical business, do you know, Mr. Barclay?

A Fifty-nine years.

MR. COBURN: That is all.

MR. McAULEY: That is all.

(Witness excused.)

MR. McAFEE: In view of the concession that has been made here by adversary counsel, I think we are through.

THE COURT: Anything further for the plaintiff?

MR. McAULEY: I would like to recall Mr. Kidd.

Floyd E. Kidd,

plaintiff, recalled, was examined and further testified as follows:

DIRECT EXAMINATION

By Mr. McAuley:

Q Mr. Kidd, following your release from the hospital

in March, March 17 or 18, along there, and prior to your subsequent admission in May of 1954, I will ask you where (167) you obtained your drinking water; what was the source?

A It was city water.

Q Knoxville city water?

A Yes, sir.

Q The same you had used previously?

A All my life.

Q What about your food supply, did it come from the same sources?

A Yes, sir. The A & P store on North Broadway.

Q That is a plug for the A & P. Did you leave Knoxville during that interim of the two periods of hospitalization?

A No, sir.

Q You remained here all the time?

A Here at all times.

MR. McAULEY: That is all.

MR. McAFEE: That is all.

(Witness excused.)

MR. McAULEY: Plaintiff rests, your Honor.

THE COURT: All right. Anything further?

MR. McAFEE: No, nothing further.

THE COURT: Let the jury be excused temporarily.

(Whereupon, the following proceedings were had in the absence of the jury.)

MR. McAFEE: If your Honor please, we want to (168) renew our motion for a directed verdict on the same grounds, and I will read them to you if you want them.

THE COURT: You may treat them as read, and let the reporter, if you desire, recopy your grounds.

MR. McAFEE: Mr. Reporter, you will recopy the motion as it appears in our previous motion.

("If your Honor please, the defendant moves the Court to direct the jury to return a verdict in favor of the defendant upon the following grounds:

No. 1. There is no proof that the plasma given to the plaintiff contained a jaundice virus. I want to amend that by saying the hepatitis virus.

No. 2. There is no proof a virus in the plasma was the cause of the plaintiff's hepatitis.

No. 3. There is no proof the plasma received by the plaintiff Kidd was adulterated within the meaning of the Tennessee Food, Drug and Cosmetic Act.

No. 4. Because the proof shows that in all cases of transfusions of plasma there is a calculated risk involved that the plasma may contain hepatitis and could cause the recipient to develop jaundice or hepatitis, and this risk was known to and assumed by the plaintiff.

No. 5. Because the undisputed evidence shows that blood plasma is used only on orders of a doctor and the action of the plaintiff's doctor in ordering and giving (169) the transfusion of plasma to the plaintiff constituted an independent intervening cause breaking the causal connection between the defendant's act and the ultimate injury sustained by the plaintiff.

And, finally, because there was no proof introduced upon which a verdict for the plaintiff can be sustained.")

MR. McAFEE: Do you want to hear an argument on it?

THE COURT: Gentlemen, I am going to submit the case to the jury.

(A discussion was had off the record.)

MR. McAFEE: There is one other ground that we want to add to the motion for a directed verdict.

MR. COBURN: The added ground is that if the Ten-

nessee statute is so construed as to bar from sale in Tennessee this product licensed by the Federal government under a Federal Act with full knowledge on the part of the Federal governmental agency, then the Tennessee statute is unconstitutional.

THE COURT: Because you say the Government is occupying that ground and it is over and above what the State does in the field which is presently occupied.

MR. COBURN: I am not saying the statute is unconstitutional. I am saying if it is construed to this meaning then it becomes unconstitutional.

(170) THE COURT: Let that be added.

(Whereupon, counsel presented oral argument on the motion for a directed verdict.)

THE COURT: Let's take a recess, gentlemen.

(A short recess was had.)

THE COURT: Call the jury in.

(Whereupon, the following proceedings were had in the presence of the jury, to-wit:)

THE COURT: Now, Mr. McAfee and Mr. McAuley, I am delivering to the reporter the requests that I refused, and in order that you may know before you get to the argument, I expect to charge those two, all others are refused.

Proceed with the argument.

(Whereupon, counsel for the respective parties presented their closing arguments to the jury.)

THE COURT: Do not overlook the instructions, ladies and gentlemen, that I gave you at noon and this morning. Don't talk to anybody of course, about this case. Don't let anybody talk to you. If there happens to be anything in the newspaper don't read the newspaper about it, or on the radio or television. If anybody undertakes to talk to you about the case tell them you are a juror. If they continue to talk

to you after that, after they know you are on the jury, report it to the Court at once.

Adjourn Court until 9 o'clock tomorrow morning.

(171) (Whereupon, at 5:01 p.m., Court adjourned until 9 o'clock a.m., November 16, 1955.)

(172) SECOND DAY OF TRIAL

(Wednesday, November 16, 1955)

(Whereupon, at 9:11 a.m. court convened pursuant to adjournment, when the following proceedings were had in the presence of the jury, to-wit:)

THE COURT: Ladies and gentlemen of the jury, this is an action by plaintiff, Floyd E. Kidd, to recover damages from Merck & Company, Inc., for injury allegedly sustained from intravenous injection of a blood plasma product manufactured and sold by the defendant, its trade name being "'Lyovac' Normal Human Plasma (Irradiated)."

Plaintiff says, that on or about March 8, 1954 he was a patient in St. Mary's Memorial Hospital, Knoxville, suffering from loss of blood due to a leg wound; that Lyovac was given to him intravenously in treatment of the blood deficiency; that the Lyovac contained a harmful substance known as serum hepatitis or SH virus; that as a result of administration of the contaminated Lyovac he developed yellow jaundice, transfusion jaundice, or serum hepatitis, a disease of the liver.

Plaintiff proceeds against defendant on a single theory of liability, namely, statutory negligence in that defendant placed on the market through channels of commerce a product which was contaminated by reason of its containing (173) a filthy substance in violation of Tennessee Code Sections 6580.3, 6580.5 and 6580.15.

These Code sections provide as follows, and I am quoting from the official code of Tennessee:

"6580.3. Prohibited Acts. — The following acts and the causing thereof within the State of Tennessee are prohibited:

"(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

"6580.5. Violations made misdemeanor. — (a) Any person who violates any of the provisions of section 6580.3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than thirty (30) days or a fine of not more than fifty ($50.00) dollars, or both such imprisonment and fine; * * *

"6580.15. Drugs or Devices Deemed Adulterated. — A drug or device shall be deemed to be adulterated:

"(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance: * * *."

(174) Plaintiff does not claim the blood plasma which was injected into his veins while he was in the St. Mary's Hospital was putrid or decomposed or was contaminated with a putrid or decomposed substance, but he does claim that it was contaminated with a filthy substance.

For answer, defendant denies there was any violation of the statute as above quoted on its part either in the manufacture or the distribution and sale of its product.

Defendant also denies that plaintiff's alleged liver disease was caused by defendant's product.

Furthermore, defendant says that blood plasma in order to remain usable and of any value for transfusion purposes cannot be made sterile or completely free of viruses, for which reasons doctors and through them their patients who

use transfusions assume the risk of the presence of a virus in the plasma. Defendant says this risk is called to the attention of users of the Lyovac by printed instructions enclosed in the package with the product, a copy of which was filed in this record and read to the jury by counsel or one of the witnesses.

Defendant further says that the sealed package in which the product leaves defendant's plant does not remain sealed until the moment of use, but there exists (175) the possibility of intervening cause of contamination for which reason enclosed instructions call attention to this possibility. In short, the defenses relied on by the defendant are: First, that the defendant did not violate any statute of the State of Tennessee in producing its product and putting it into the channel to be shipped into Tennessee; Second, defendant says that there is an absence of proximate cause; Third, the risk was unavoidable.

Under the theory of unavoidable risk, it is defendant's position that blood plasma, such as produced and marketed by the defendant, cannot be sterile and still be usable; also, that because of its great usefulness its manufacture is properly licensed, its marketing sought and desired; further, that because of its sources in human blood donors the risk of its containing the objectionable virus is one that cannot be avoided; that this fact is made known to physicians who use the plasma; that physicians are informed that disease such as plaintiff's, is sometimes transmitted by injection of the plasma; that as physicians they assume the risk of transmitting the disease in this fashion, and that because of the relation of doctor and patient the patient also assumes that risk.

The theory involved in this defense is of necessity subject to conditions. Assumption of risk by doctor (176) and patient presupposes that the product being used complies with

the standards of purity required in its manufacture. They cannot be held to have assumed the risk of below-standard products or of a plasma that is placed upon the market in violation of law.

Here plaintiff seeks to hold defendant liable on the theory that the plasma complained of did not meet the standard required by the Tennessee statute heretofore quoted.

In Tennessee the courts have held that violation of a prohibitory statute is negligence per se, which means that where a defendant is liable for injury inflicted upon a plaintiff on the theory of negligence, plaintiff proves negligence when he proves that the statute was violated. The violation is negligence in and of itself.

The Tennessee Food, Drug and Cosmetic Act prohibits the manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated. It provides that a drug or device shall be deemed adulterated "If it consists in whole or in part of any filthy substance."

Thus the Tennessee standard is set up. Was the offending plasma an adulterated drug or device, as here defined? That is a question the jury must answer in this (177) case. It was adulterated if it contained any filthy substance. When the plasma was administered in this case it was assumed by the doctor and the patient that it did not contain any filthy substance, as that term is used in the Tennessee statute.

In Webster's Collegiate Dictionary, which was read from by counsel and by the witnesses in this case, filth is defined as "Foul matter; anything that soils or defiles disgustingly."

Webster defines filthy as, "Defiled with filth; disgustingly dirty," or "foul, polluting, impure."

A substance may be filthy because of its own nature or because of filthy substances which have been added to it.

That human blood and blood plasma are transferred from one person to another, has become common knowledge. Human blood in its natural state is not regarded as filthy. However, it can become contaminated in such fashion as to make it filthy.

Plaintiff's case is based upon the allegation or the claim that the blood plasma in question was thus contaminated for the reason that it contained a virus that was a man-producing disease, which plaintiff calls the virus of serum hepatitis. This presents a factual question for the jury to answer from the evidence in this case, (178) especially the evidence which came from the expert witnesses as well as the evidence which came from the other witnesses in the case. To laymen, filthy can be easily understood in terms of experience. However, the layman is not familiar with things which exist in the world of the microscope or in the world which cannot be observed through the microscope. Whether presence of a virus in blood renders the plasma filthy, is a question to be answered by witnesses whose experience has familiarized them with viruses and the effect of their presence in blood plasma. If their answer is yes, that will present the second question: Was the blood plasma used in this instance thus contaminated? And if so did it produce plaintiff's disease of yellow jaundice.

Now plaintiff has the burden of proof on these matters. That is, by a preponderance of the evidence it must appear that plaintiff's allegations are sustained. Those allegations, proof of which is necessary to make out a case of liability, are: (1) that the plasma violated the statutory standard; (2) that the plasma, by reason of its contamination, caused plaintiff to contract the complained of disease of yellow jaundice.

Preponderance of evidence means that the evidence in support of plaintiff's allegations outweighs the evidence

(179) to the contrary. Unless it does preponderate in favor of plaintiff, the burden of proof has not been carried by plaintiff and the verdict should be for the defendant.

Evidence is of two kinds, direct and indirect. Direct evidence is that which a witness acquired through his own senses — sight, smell, taste, sound or touch. Sight includes what a person sees not only under normal conditions of existence, but also by aid of the microscope or by observation of chemical reactions and the physical properties of substances which are contacted in physical, chemical and biological laboratories. The other senses, also, operate in fields of discovery, including both the ordinary and the extraordinary. Whatever is discovered or observed by the senses, is direct evidence whether it be ordinary or of a highly technical character.

Indirect evidence consists of inferences properly to be drawn from direct evidence. The two together comprise what is frequently called circumstantial evidence. It consists of inferring that one thing is true because another is known to be true.

Circumstantial evidence plays an important role in the matter of causation, especially with relation to disease. If it has been proved here that the plasma given to plaintiff contained contamination in violation of the (180) statute, that proof would be direct evidence because arrived at through the senses. Again, if it has been proved that plaintiff contracted the disease complained of, that proof would be direct evidence, because arrived at through the senses. But proof of these two facts would leave a gap still to be filled, or a question to be answered, namely, whether the injection of contaminated plasma caused plaintiff's disease. Could it have been caused in some other way? It is here that inferences come into play. From all of the related facts which have been proved, should the inference be that the

plasma caused the disease? Or should the inference be that it had other cause or causes? Proximate cause must have existed between the allegedly harmful agency and the disease, that is, the one must have been the direct cause of the other. From the time element involved, from symptoms, from experience encountered in similar cases, from opinions of the experts, an inference must be drawn. But it is not proper to base one inference upon another inference. That inference may be that proximate cause did exist, or it may be that proximate cause did not exist. It is the jury's function to determine which is the correct inference.

In this connection I charge you as requested by (181) the plaintiff, that if you find from the testimony that the illness or injury to plaintiff, if any, might have equally as well have resulted from some cause other than the transfusion of the plasma, you will find for the defendant.

Again I charge you as requested by the defendant — did I say as requested by the plaintiff in the first one?

THE REPORTER: Yes, you did, your Honor.

THE COURT: I meant defendant. That charge is requested by the defendant instead of the plaintiff.

I again charge you at this time as was requested by the defendant, that before you can find for the plaintiff you must find that the hepatitis virus was actually in the defendant's plasma, and that this same virus was the proximate cause of the plaintiff's jaundice.

Causation sometimes is broken by what is known as intervening cause. However, intervening cause is not acceptable as a defense where it is foreseeable that the intervening cause will occur. That the doctor who administered the plasma made a decision whether to use it or not use it, was something foreseeable. Moreover, as the plasma was in extensive use, it was reasonably foreseeable that it would be used in plaintiff's case, his (182) condition being such

that a blood transfusion, or its equivalent, was called for. Intervening cause, where thus foreseeable, does not destroy original causation.

Evidence may be defined as something which serves as a means to make facts clear and plain to the jury. It consists chiefly of related facts, exhibits and objects, brought to the attention of the jury through the medium of witnesses.

Ordinarily opinions of witnesses are not admissible in evidence, but only their statement of facts. The rule is different where the person testifying is an expert witness. His opinion is sometimes admitted. When so admitted, it serves the same purpose as other evidence, that of making clear and plain the facts or conclusions sought to be established.

An expert witness is one who possesses special or technical knowledge or skill upon the subject about which he testifies, that is, upon a subject with which ordinary men are not familiar. An expert, of course, may testify as to facts, like any other witness. If an expert witness testifies as to facts, his testimony, like that of other witnesses, should be weighed as to credibility and with consideration as to the character, capacity, training, skill, and interest, or want of interest, of the witness.

(183) But the term "expert witness" is usually applied to a witness who is presented for the purpose of having him express an opinion. Sometimes the opinion of an expert witness is based upon facts in the case about which there is no dispute and which are known to the expert. Sometimes his opinion is based upon a statement of facts for the moment merely supposed to exist. If his opinion is based upon facts proved or admitted to be true, the opinion may be considered by the jury. But if it is based upon supposed facts, not yet proved or admitted, his opinion may not be considered unless the supposed facts are afterwards established.

In one case the opinion is based on facts already established. In the other it is based on facts which, it is expected, will be established. That is, it is an opinion in advance of proof. Unless the supposed facts are forthcoming, the opinion based on them will not be considered.

Where a person is permitted to testify by giving his expert opinion, that means that the court considers him qualified to testify as an expert witness. It does not mean that the jury must accept what he says as an established fact, or as proving the plaintiff's or defendant's contention, as the case may be. The expert's opinion may be of great weight or it may be of little or (184) no worth. Though coming from an expert, it is still opinion evidence. It should be received by the jury with appropriate caution and for the purpose in which the jury receives other evidence, namely, as an aid to arriving at a correct conclusion.

You, the Jury, are the sole and exclusive judges of the testimony and of the weight and credibility that you will give to the swearing of the witnesses, and in weighing the evidence you will look to the demeanor of the witness while he was upon the witness stand, to his intelligence or lack of intelligence, to any bias or prejudice or feeling that may be manifested, and to his relationship to any of the parties in the case, his interest or lack of interest in the outcome of the lawsuit, his means of knowledge of the facts about which he testifies, the reasonableness or unreasonableness of the story that he told. All of those things you will take into consideration in weighing the testimony, and you will give greater weight to that witness or those witnesses who, in your opinion, have more truthfully detailed the true facts of the case.

Before the case is left to the jury, a word of caution seems appropriate. It concerns the subject of risk, and it is men-

tioned here as a reminder that the jury (185) should not be misled by irrelevant or immaterial or false issues.

In its answer in this case, the defendant has averred, or stated, that with each package of its product it has included a statement calling attention to the risk involved in use of the plasma, blood plasma, the risk being that the disease which afflicted the plaintiff sometimes results. The position of defendant is something like this: "Here is our product. It has been instrumental in saving many lives. You may use it or not use it, as you like. It may save your life, or it may kill you, or give you a serious disease. The choice is up to you whether to use it. Whatever the result, you face it upon the basis of a calculated risk. If you use it after we have warned you and it makes you sick, it is your misfortune and not ours."

From the viewpoint of the one who uses it and who is made sick, as plaintiff claims to have been made sick in this case, the reasoning runs something like this: "You are in business for profit. You are placing upon the market a product which will help many, but which may also cause illness to a few, of which I am one. If your product contains something which may make some of us sick, we will sue you for damages. So, when you market your (186) product, you do so upon the basis of a calculated risk. The choice is up to you. If we sue you, it is your misfortune, not ours, or not mine."

As heretofore stated, these conflicting viewpoints are mentioned by way of caution to the jury. They present a false issue. You, as jurors, are not called upon to determine matters of public policy. The questions you are asked to answer are questions of fact and to be answered from the evidence which was given in the case. In order that you may have them clearly before you as you take the case under advisement, they are at this time restated.

First: Did the defendant violate the Tennessee statute by placing upon the market a drug or device which was adulterated in the sense that it contained some filthy substance?

Second: If it was an adulterated product did it proximately cause plaintiff's illness; that is, was it the immediate and proximate cause of plaintiff's illness?

If your answers to these questions are yes, or in the affirmative, your verdict should be for the plaintiff, otherwise your verdict should be for the defendant, or if your answers to those questions are in the negative, or if your answer to either of those questions (187) is in the negative, your verdict should be for the defendant.

If it is for the defendant, that ends the lawsuit.

If the verdict is for the plaintiff, there should be an award of damages. Plaintiff is suing for $50,000.00. He claims as his elements of damage: A disease of the liver known by various names; he claims pain and suffering by reason of this disease; medical and hospital expenses; loss of earnings, future expenses, suffering, and monetary losses. All of these elements are recoverable in law if and to the extent proved as having been proximately caused by defendant's product. But damages may not be speculative; they may not be based on guess or conjecture. Between the wrong and the damages, proximate cause must have existed. Future expenses, suffering and losses should be limited to such as the proof shows are reasonably certain to follow as a proximate result of defendant's violation of the law, if there was such violation.

The jury may not award more than the amount sued for. It may award less. The theory of damages is fair compensation for the injuries and losses sustained.

Let the jury be excused temporarily.

(Whereupon, the following proceedings were had (188) out of the presence and hearing of the jury.)

THE COURT: Does the plaintiff have any objection to this charge, or any further request other than those which have been ruled upon by the Court?

MR. McAULEY: Only one, your Honor. It is the feeling of the plaintiff that the ordinary definition of words should be applicable rather than the scientific definition. I believe that was called to your Honor's attention earlier.

THE COURT: All right, sir. Anything further? I overrule the objection.

MR. McAULEY: Very well, your Honor.

THE COURT: Is it an objection or a request?

MR. McAULEY: Well, it is a request. Well, the charge was given — as ordinarily given it would be the scientific definition, and so this is in the nature of a request that the jury be instructed that they should give it the ordinary and not the scientific meaning.

THE COURT: I refuse that request, because I feel I have covered that section.

MR. McAULEY: Note our exception. That is the only thing we have.

THE COURT: Does the defendant have any objection to this charge or any further request other than those (189) that have been passed on?

MR. COBURN: If your Honor please, we would object to that portion, or those portions of the charge which give to the jury the question of not whether the virus was present in the plasma but whether the virus present in the plasma was a filthy product within the meaning of the Tennessee act. We think that is a question of law and not of fact and should not be submitted to the jury.

We also would wish to enter an objection to those portions of the charge which deal with matters of assumption of

risk and intervening cause. Because, although we understand from the concluding portion of your Honor's charge that those issues are not left with the jury, they are not among the issues which you instructed the jury they were to consider in arriving at their verdict, nevertheless their attention was drawn to those points which we feel may be confusing to the jury, and we therefore wish to object to that. We consider those questions of law.

THE COURT: Those objections are overruled.

Is there anything further before I call the jury back?

MR. McAULEY: No, your Honor.

(190) THE COURT: Call the jury in.

(Whereupon, the following proceedings were had in the presence and hearing of the jury, to-wit:)

THE COURT: The two alternate jurors may step aside. Don't leave because we have another case.

Ladies and gentlemen, you may now retire for the consideration of your verdict. After you have arrived at your verdict return with it in open court.

(Whereupon, the Jury retired to consider of its verdict, after which it reported into open court and the following proceedings were had, to-wit:)

THE COURT: You gentlemen waive the call of this jury?

MR. McAULEY: Yes, your Honor.

MR. McAFEE: Yes, your Honor.

THE COURT: Ladies and gentlemen, have you agreed upon your verdict?

THE FOREMAN: We have, your Honor.

THE COURT: What is your verdict?

THE FOREMAN: We find our verdict in favor of the plaintiff, damage $12,000.00.

THE COURT: So say you all?

(The jury indicated in the affirmative.)

MR. McAFEE: I didn't understand the figure.

(191) THE COURT: Twelve Thousand Dollars.

The jurors are excused until 9 o'clock Monday morning.

(Whereupon, this is all the evidence offered and proceedings had on the trial of the above entitled cause.)

(192) PLAINTIFF'S SPECIAL REQUEST NO. 1 (Refused.).

Proof of possibilities or even probabilities opposed to circumstantial evidence relied on by plaintiff will not overcome as a matter of law the force of the circumstantial evidence, and in such case a verdict based on the whole evidence is not the product of speculation and conjecture.

(Headnote 6. Evidence, Key 587. Johnson v. Ely, 205 S.W. 2d 759.)

* * * * *

PLAINTIFF'S SPECIAL REQUEST NO. 2. (Refused.)

Question is whether it is a "filthy" substance, and in this respect the word is intended to be given its ordinary meaning and now confined to any scientific or medical definition.

* * * * *

(193) DEFENDANT'S SPECIAL REQUEST NO. 3. (Refused.)

I further charge you, ladies and gentlemen of the jury, that the term "contaminated with filth" contained in the Tennessee Food, Drug & Cosmetic Act does not place the burden upon defendant of seeing that its blood plasma is absolutely free from contamination in all events but only so far as possible. Accordingly, the defendant is not liable to the plaintiff if you find as a fact that defendant, as far as possible, in the light of existing knowledge did all that it could to prevent the presence of the virus in the plasma.

* * * * *

Special Requests

DEFENDANT'S SPECIAL REQUEST NO. 4. (Refused.)

I further charge you, ladies and gentlemen of the jury, that if you find from the proof that there is neither a means of detecting the presence of the jaundice-producing agent in the donor's blood nor a practical method of treating the blood or blood plasma used for transfusions so that the danger may be eliminated, then the defendant is not guilty of violating the Tennessee Food, Drug & Cosmetics Act and your verdict should be for the defendant.

(194) (Perlmutter vs. Beth David Hospital, 123 N.E. 2d, 792 (Court of Appeals of New York, 1954)

(Tennessee Food, Drug and Cosmetic Act, Section 6580.2, Sub-Section O.)

* * * * *

DEFENDANT'S SPECIAL REQUEST NO. 5. (Refused.)

I charge you, ladies and gentlemen of the jury, that merely because a substance is in some instances harmful does not necessarily make such substance filthy within the Tennessee Food, Drug & Cosmetics Act.

(Perlmutter vs. Beth David Hospital, 123 N.E. 2d, 792 (Court of Appeals of New York, 1054)

(Tennessee Food, Drug and Cosmetic Act, Section 6580.2, Sub-Section O.)

* * * * *

DEFENDANT'S SPECIAL REQUEST NO. 6. (Refused.)

I further charge you, ladies and gentlemen of the jury, that the term "contaminated with filth" contained in the Tennessee Food, Drug and Cosmetic Act (195) requires the defendant to protect its product from dust, dirt, and as far as possible from all foreign or injurious contamination. Accordingly, the defendant is not liable to the plaintiff if you find as a fact that defendant, as far as possible, in the light of existing knowledge, did all that it could to prevent

the presence of the virus in the plasma while retaining its usefulness as plasma.

(Tennessee Food, Drug and Cosmetic Act, Section 6580.2, Sub-Section O.)

* * * * *

DEFENDANT'S SPECIAL REQUEST NO. 7. (Refused.)

I further charge you, ladies and gentlemen of the jury, that before you can find for the plaintiff you must not only find that the hepatitis virus was in the plaintiff's plasma and that same virus was the sole and proximate cause of plaintiff's injury, but you must go further and find that the defendant failed, as far as possible, to prevent the virus from being in the plasma.

(Tennessee Food, Drug and Cosmetic Act, Section 6580.2, Sub-Section O.)

* * * * *

(196) DEFENDANT'S SPECIAL REQUEST NO. 8. (Refused.)

I further charge you, ladies and gentlemen of the jury, the fact that plasma may contain a hepatitis virus in and of itself does not make such plasma contaminated with a filthy substance within the meaning of the Tennessee Food, Drug & Cosmetic Act.

(Tennessee Food, Drug & Cosmetic Act, Section 6580.2, Sub-Section O.)

* * * * *

DEFENDANT'S SPECIAL REQUEST NO. 9. (Refused.)

I further charge you, ladies and gentlemen of the jury, that since there is neither a means of detecting the presence of the jaundice-producing agent in the donor's blood nor a practical method of treating the blood or blood plasma used for transfusions so that the danger may be eliminated, the

mere fact that plasma may contain a hepatitis virus in and of itself does not make such plasma contaminated with a filthy substance within the meaning of the Tennessee Food, Drug and Cosmetic Act.

(Perlmutter v. Beth David Hospital, 123 N. E. 2d, 792 (Court of Appeals of New York, 1954.)

Tennessee Food, Drug and Cosmetic Act, Section 6580.2, Sub-Section O.)

VERDICT

(November 16, 1955)

Came the parties by their attorneys, and came the same jury as of yesterday who having heard argument of counsel and the charge of the court; at the close of same the two alternate jurors, Ed Rickard and Mrs. William Haynes, were excused from further service. Thereupon the jury having fully considered of their verdict returned into open court and upon their oaths do say that they find the issues joined in favor of plaintiff, and against the defendant, in the amount of $12,000.00.

DEFENDANT'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT JOINED WITH ITS MOTION FOR A NEW TRIAL.

(Filed November 22, 1955).

I.

Now comes the defendant by Joseph A. McAfee, its attorney, and moves that the verdict and judgment heretofore entered in the above entitled cause for plaintiff be set aside and that judgment be entered for defendant in accordance with is previous motion for a directed verdict made at the conclusion of all of the evidence introduced in this cause, which motion contained the following grounds:

Defendant's Motion for Judgment Notwithstanding Verdict Joined With its Motion for New Trial

1. There is no proof that the plasma given to the plaintiff contained the hepatitis virus.

2. There is no proof a virus in the plasma was the cause of the plaintiff's hepatitis.

3. There is no proof the plasma received by the plaintiff Kidd was adulterated within the meaning of the Tennessee Food, Drug and Cosmetic Act.

4. Because the proof shows that in all cases of transfusions of plasma there is a calculated risk involved that the plasma may contain hepatitis and could cause the recipient to develop jaundice or hepatitis, and this risk was known to and assumed by the plaintiff.

5. Because the undisputed evidence shows that blood plasma is used only on orders of a doctor and the action of the plaintiff's doctor in ordering and giving the transfusion of plasma to the plaintiff constituted an independent intervening cause breaking the causal connection between the defendant's act and the ultimate injury sustained by the plaintiff.

6. Because there was no proof introduced upon which a verdict for the plaintiff can be sustained.

7. That if the Tennessee statute is so construed as to bar from sale in Tennessee this product licensed by the Federal government under a Federal Act with full knowledge on the part of the Federal governmental agency, then the Tennessee statute is unconstitutional.

II.

Now comes the defendant by Joseph A. McAfee, its attorney, and moves the Court to set aside the verdict and judgment heretofore entered in this cause and grant the defendant a new trial therein.

And for grounds of said motion the defendant shows to the Court the following, to-wit:

Defendant's Motion for Judgment Notwithstanding Verdict Joined With its Motion for New Trial

1. The Court erred in refusing to sustain the defendant's motion for a directed verdict made at the close of all the proof in the case.

2. The verdict is contrary to the law in the case.

3. The verdict is contrary to the evidence in the case.

4. The verdict is contrary to the law and evidence in the case.

5. Because there is no evidence showing privity of contract between plaintiff and defendant and the rule requiring such privity still prevails in Tennessee in those cases imposing strict liability based on violations of the Tennessee Food, Drug and Cosmetic Act.

6. The Court erred in refusing to give to the jury the following instructions requested by the defendant:

(a) I further charge you, Gentlemen of the Jury, that if you find from the proof that there is neither a means of detecting the presence of the jaundice-producing agent in the donor's blood nor a practical method of treating the blood or blood plasma used for transfusions so that the danger may be eliminated, then the defendant is not guilty of violating the Tennessee Food, Drug and Cosmetic Act and your verdict should be for the defendant.

(b) I further charge you, Gentlemen of the Jury, that the term "contaminated with filth" contained in the Tennessee Food, Drug and Cosmetic Act requires the defendant to protect from dust, dirt, and as far as possible from all foreign or injurious contamination. Accordingly, the defendant is not liable to the plaintiff if you find as a fact that defendant, as far as possible, in the light of existing knowledge, did all that it could to prevent the presence of the virus in the plasma while retaining its usefulness as plasma.

Defendant's Motion for Judgment Notwithstanding Verdict Joined With its Motion for New Trial

(c) I further charge you, Gentlemen of the Jury, that before you can find for the plaintiff you must not only find that the hepatitis virus was in the plaintiff's plasma and that same virus was the sole and proximate cause of plaintiff's injury, but you must go further and find that the defendant failed as far as possible, to prevent the virus from being in the plasma.

(d) I further charge you, Gentlemen of the Jury, that since there is neither a means of detecting the presence of the jaundice-producing agent in the donor's blood nor a practical method of treating the blood or blood plasma used for transfusions so that the danger may be eliminated, the mere fact that plasma may contain a hepatitis virus in and of itself does not make such plasma contaminated with a filthy substance within the meaning of the Tennessee Food, Drug and Cosmetic Act.

7. The Court gave the following improper instructions to the jury:

(a) Causation sometimes is broken by what is known as an intervening cause. However, intervening cause is not acceptable as a defense where it is foreseeable that the intervening cause will occur. That the doctor who administered the plasma made a decision to use it or not use it, was something foreseeable. Moreover, as the plasma was in extensive use, it was reasonably foreseeable that it would be used in plaintiff's case, his condition being such that a blood transfusion, or its equivalent, was called for. Intervening cause, where thus foreseeable, does not destroy original causation.

(b) The Tennessee Food, Drug and Cosmetic Act prohibits the manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated. It provides that a drug or device shall be deemed adulterated "If it consists in whole or in part of any filthy substance."

Defendant's Motion for Judgment Notwithstanding Verdict Joined With its Motion for New Trial

Thus the Tennessee standard is set up. Was the offending plasma an adulterated drug or device, as here defined? That is a question the jury must answer in this case. It was adulterated if it contained any filthy substance. When the plasma was administered in this case it was assumed by the doctor and the patient that it did not contain any filthy substance, as that term is used in the Tennessee statute.

And then again repeated this instruction in his charge as follows:

First: Did the defendant violate the Tennessee statute by placing upon the market a drug or device which was adulterated in the sense that it contained some filthy substance?

(c) Before the case is left to the jury, a word of caution seems appropriate. It concerns the subject of risk, and it is mentioned here as a reminder that the jury should not be misled by irrelevant or immaterial or false issues.

In its answer in this case, the defendant has averred, or stated, that with each package of its product it has included a statement calling attention to the risk involved in use of the plasma, blood plasma, the risk being that the disease which afflicted the plaintiff sometimes results. The position of defendant is something like this: "Here is our product. It has been instrumental in saving many lives. You may use it or not use it, as you like. It may save your life, or it may kill you, or give you a serious disease. The choice is up to you whether to use it. Whatever the result, you face it upon the basis of a calculated risk. If you use it after we have warned you and it makes you sick, it is your misfortune and not ours."

From the viewpoint of the one who uses it and who is made sick, as plaintiff claims to have been made sick in this case, the reasoning runs something like this: "You are in business for profit. You are placing upon the market a product which will help many, but which may also cause illness to a few, of which I am one. It

your product contains something which may make some of us sick, we will sue you for damages. So, when you market your product, you do so upon the basis of a calculated risk. The choice is up to you. If we sue you, it is your misfortune, not ours, or not mine."

(d) Under the theory of unavoidable risk, it is defendant's position that blood plasma, such as produced and marketed by the defendant, cannot be sterile and still be usable; also, that because of its great usefulness its manufacture is properly licensed, its marketing sought and desired; further, that because of its sources in human blood donors the risk of its containing the objectionable virus is one that cannot be avoided; that this fact is made known to physicians who use the plasma; that physicians are informed that disease, such as plaintiff's, is sometimes transmitted by injection of the plasma; that as physicians they assume the risk of transmitting the disease in this fashion, and that because of the relation of doctor and patient the patient also assumes that risk.

The theory involved in this defense is of necessity subject to conditions. Assumption of risk by doctor and patient presupposes that the product being used complies with the standards of purity required in its manufacture. They cannot be held to have assumed the risk of below-standard products or of a plasma that is placed upon the market in violation of law.

8. The verdict rendered in this case is excessive.

9. There is no proof the plasma received by the plaintiff Kidd was adulterated within the meaning of the Tennessee Food, Drug and Cosmetic Act.

Wherefore, and on account of which defendant moves the Court to set aside the verdict of the jury and the judgment rendered thereon and to grant defendant a new trial.

(Signed) JOSEPH A. McAFEE,
Attorney for Defendant

Defendant's Motion for Judgment Notwithstanding Verdict Joined With its Motion for New Trial

I certify that a copy of the foregoing motion was mailed to Mr. Ben F. McAuley and Mr. Frank Marsh, attorneys for plaintiff, on this the 22 day of November, 1955.

(Signed) JOSEPH A. McAFEE.
M. W. Burton.

ORDER OVERRULING DEFENDANT'S MOTION FOR JUDGMENT N.O.V. AND ITS MOTION FOR A NEW TRIAL.

(Filed March 19, 1956).

Defendant on several grounds has moved that verdict and judgment for plaintiff be set aside and that judgment be entered for defendant or, in the alternative, that defendant be granted a new trial. Forceful arguments and briefs have been presented for and against the relief sought, in consideration of which it has been especially necessary to separate legal questions from those respecting public policy, business, and humanitarian enterprise.

Recovery by plaintiff was contingent upon proof that he was made ill by administration of the blood plasma placed upon the market by defendant, that the plasma contained hepatitis virus, and that the plasma for that reason was adulterated within the meaning of the Tennessee Food and Drug Act. Of necessity proof of the presence of hepatitis virus in the plasma and of its causation to plaintiff's illness, was circumstantial. Significant circumstances were administration of the plasma and after the usual incubation period appearance of illness in the form of serum hepatitis, plasma according to medical testimony being a known cause of such illness. From those circumstances the jury inferred existence of virus in the plasma, as well as causation between the virus and the subsequent appearance of the disease.

Order Overruling Defendant's Motion for Judgment N.O.V. and Its Motion for a New Trial

That the virus was present and caused plaintiff's illness resulted in liability for the further reason that the plasma with its virus content was found to have been an adulterated drug or device, in violation of the food and drug act. The necessary implication of that finding is that the plasma consisted in whole or in part of a filthy, putrid, or decomposed substance; in this case proof of adulteration having its emphasis on the term filthy. That term has its dictionary definition, which was given to the jury. The Tennessee Food and Drug Act itself furnished no definition. Medical testimony on the subject was divided with respect to the virus which, that testimony alone considered, gave the jury a choice of believing that the virus was or was not filthy.

Why they chose to find with those who testified that the hepatitis virus was a filthy substance, is, of course, unexplained. In so finding, however, the jurors were not required to base inference upon inference. There was proof in support of the general proposition that hepatitis virus is at times contained in blood plasma, also that it sometimes produces the dangerous and loathsome disease of serum hepatitis, or jaundice. In that situation it was permissible for the jury to find without inference but as a fact that hepatitis virus is filthy, and that plasma containing it is adulterated.

Violation and causation, essential ingredients of plaintiff's case, both had substantial support in the evidence. It is ordered, therefore, that defendant's motion be and it hereby is, denied.

Entered:

Signed: Robert Taylor,

Judge

NOTICE OF APPEAL

(Filed April 5, 1956)

Notice is given that Merck & Company, Inc., defendant above named, hereby appeals to the United States Court of Appeals for the Sixth Circuit from the final order or judgment entered in this action on March 19, 1956.

(Signed) JOSEPH McAFEE,
Attorney for Merck & Co. Inc.,
312 Park National Bank Building,
Knoxville, Tennessee.

I acknowledge receipt of a copy of the foregoing notice this April 5, 1956.

(Signed) BEN F. McAULEY,
Attorney for Plaintiff.

DEFENDANT'S EXHIBIT NO. 1

* * * * *

RISK OF SERUM HEPATITIS

It is generally recognized that some samples of human blood contain a virus capable of causing so-called serum hepatitis or serum jaundice following transfusion.[15] Although the relationship of homologous serum hepatitis to infectious hepatitis is not entirely clear, present indications are that the icterogenic agent of both diseases is a virus.

Despite careful selection of blood donors under strict supervision, there is still the possibility that some blood will contain the hepatitis virus, since no laboratory procedure exists for its detection in the blood.

In recent years methods have been developed for the sterilization of suspensions containing bacteria and viruses.[16-18] In controlled studies carried out in human subjects, using both irradiated and nonirradiated serum, hepatitis did not occur in those individuals who received injections of irradiated material.[18,19] Toxic effects due to radiation of plasma were not observed following injection of this material and there was no deleterious effect on the therapeutic value of the plasma.[18,20] Radiation of plasma with ultraviolet light was accordingly adopted as a requirement by the National Institutes of Health.

More recently, similar controlled studies in human subjects were carried out using plasma irradiated with ultraviolet light in compliance with the regulations of the National Institutes of Health. In these new studies the radiation process was not effective in preventing the transmission of homologous serum hepatitis.

In addition to the studies referred to above, there have been several reports of hepatitis following the injection of irradiated human plasma in which, despite other well

recognized sources of infection,[21-23] it appears that the virus was transmitted through the plasma.[24-27] The occurrence of serum hepatitis has also been reported following the injection of irradiated human mumps immune serum.[28]

On the basis of the limited evidence now available, the physician should assume that the use of irradiated human plasma still may involve a calculated risk that the patient may develop serum hepatitis.

* * * * *

STIPULATION

It is stipulated between the parties that the photostatic copy of an article published by the Committee on Medicolegal Problems of the American Medical Association on the subject Medicolegal Aspects of Blood Tranfusion filed as Exhibit No. 2 to the deposition of Dr. J. E. Acker, is a true and correct copy of the original of which it purports to be and that the same may be introduced in evidence in this cause, subject only to the objections for competency, relevancy and materiality.

(Signed) BEN F. McAULEY
Attorney for Plaintiff

(Signed) JOSEPH A. McAFEE
Attorney for Defendant

DEFENDANT'S EXHIBIT NO. 2

* * * * *

RISK OF SERUM HEPATITIS

It is generally recognized that some samples of human blood contain a virus capable of causing so-called serum hepatitis or serum jaundice following transfusion.[15] Al-

though the relationship of homologous serum hepatitis to infectious hepatitis is not entirely clear, present indications are that the icterogenic agent of both diseases is a virus. The reported morbidity rate of serum hepatitis varies from 1.5 per cent among patients who receive plasma from small pools (5 to 10 donors) to 4.5 per cent to 12 per cent in patients receiving plasma from large pools (1000 to 5000 donors).[16]

Despite careful selection of blood donors under strict supervision, there is still the possibility that some blood will contain the hepatitis virus, since no laboratory procedure exists for its detection in the blood.

In recent years methods have been developed for the sterilization of suspensions containing bacteria and viruses.[17, 18, 19] In controlled studies carried out in human subjects, using both irradiated and nonirradiated serum, hepatitis did not occur in those individuals who received injections of irradiated material.[19, 20] Toxic effects due to radiation of plasma were not observed following injection of this material and there was no deleterious effect on the therapeutic value of the plasma.[19,21] Radiation of plasma with ultraviolet light was accordingly adopted as a requirement by the National Institutes of Health.

More recently, similar, as yet unreported, controlled studies in human subjects were carried out using plasma irradiated with ultraviolet light by a technique complying with the regulations of the National Institutes of Health, but differing in some respects from that employed in the original studies and that employed in the manufacture of 'Lyovac' Normal Human Plasma. In these new studies the radiation process that was used was not effective in preventing the transmission of homologous serum hepatitis.

In addition to the studies referred to above, there have been several reports of hepatitis following the injection of

irradiated human plasma in which, despite other well recognized sources of infection,[22-24] it appears that the virus was transmitted through the plasma.[25-28] The occurrence of serum hepatitis has also been reported following the injection of irradiated human mumps immune serum.[29]

On the basis of the limited evidence now available, the physician should assume that the use of irradiated human plasma still may involve a calculated risk that the patient may develop serum hepatitis.

* * * * *

STIPULATION

It is stipuated between the parties that the attached photostatic copy of the Surgical or Medical Permit, dated March 8, 1954, and executed on said date by Mrs. Floyd Kidd, wife of the plaintiff, is a true and correct copy of the original of which it purports to be, and that the same may be introduced in evidence in this cause, subject only to the objections for competency, relevancy and materiality.

(Signed) BEN F. McAULEY
Attorney for Plaintiff

(Signed) JOSEPH A. McAFEE
Attorney for Defendant

SAINT MARY'S MEMORIAL HOSPITAL

SURGICAL OR MEDICAL PERMIT

I, the undersigned _____

a patient or a friend of patient Freda Edgar Kidd

at Saint Mary's Memorial Hospital, hereby consent to any surgical or medical procedure the Surgeon or Physician may deem necessary.

Signed: Freda Edgar Kidd

I certify the foregoing information was read to person signing this consent and his or her signature witnessed by me

Witness: Li Brewster Date 3-8-54

NOTICE TO PATIENTS

IMPORTANT! Patients will please understand the following:

Patients are requested to send clothing and valuables home. The Hospital will be responsible for money, jewelry and other valuables when same are left at the Business Office and a receipt therefor is exhibited. The Hospital will under no circumstances be liable for any other personal property of the patient. No employee of the Hospital has authority to make any exception to this rule.

Freda Edgar Kidd

3

2587

174a – Exhibit No. 4

[redacted]

BULLETIN OF
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VIRAL HEPATITIS*

RODERICK MURRAY

Assistant Chief, Laboratory of Biologics Control, National Microbiological Institute, National Institutes of Health, Bethesda, Maryland

VIRAL hepatitis represents one of the most important problems in the field of infectious diseases today. The military aspects have been frequently emphasized. These include loss of time, prolonged hospitalization and prolonged convalescence, and are also important, although perhaps not as pressing, in civil life, not only in this country but throughout the whole world. The number of articles appearing in medical publications, upwards of 2,000 during the past five years, indicates the concern of the writers with these matters and deal particularly with epidemiology, prevention and treatment.

The control of infectious diseases can be extremely difficult when the etiological agent cannot be isolated. This is well illustrated in the case of both infectious hepatitis (Virus A) and homologous serum hepatitis (Virus B).

Although a considerable amount of work has been done during and since World War II, and much valuable information has been obtained,

* Presented at the 27th Graduate Fortnight of The New York Academy of Medicine, October 20, 1954.
From the Laboratory of Biologics Control, National Microbiological Institute, National Institutes of Health, Public Health Service, U. S. Department of Health, Education, and Welfare, Bethesda, Md.

there have been few significant advances in knowledge concerning the etiology, specific diagnosis or treatment of these diseases. The main difficulty or bar to the acquisition of firm information resides in the fact that it has not been possible thus far to transmit the illness to animals other than man or to develop any serological or other specific tests for the agents or to identify specific antibodies. A great many attempts have been made to adapt the agent(s) to some animal and to pass them in the chick embryo or tissue cultures with negative or at most doubtful results. A review of what has been done and an evaluation of the results obtained in these directions has recently been attempted in a symposium held under the joint sponsorship of the National Research Council and of the Commission on Virus and Rickettsial Diseases of the Armed Forces Epidemiological Board.[1] The general conclusion was that in no case could it be proved beyond question that adaptation or passage had been achieved. It is generally felt that progress in obtaining knowledge about these illnesses will not be great until some laboratory methods of detecting or propagating the agents are devised. For a rather succinct discussion and review of the information available, reference may be made to the First Report of the Expert Committee on Hepatitis of the World Health Organization[2] or a recent review by Dr. F. O. MacCallum in the British Medical Bulletin which covered essentially similar ground.[3]

The fact that both viruses may be transmitted by inoculation and that the illnesses produced are for the most part similar suggests that they may be related. Both have been demonstrated to pass through filters capable of removing bacteria, and in the case of Virus B, material which was passed through a gradocol membrane of average pore size 52 mu remained infectious, indicating a dimension (in one direction at least) of 26 mu or less.[4] These viruses appear to be unusually resistant to inactivation by physical and chemical agents. This has certainly been demonstrated in the case of Virus B which is able to withstand applications of heat or ultraviolet energy at levels many times that required for the inactivation of most other viruses. In the case of Virus A the mode of transmission is usually by the fecal-oral route, but it can also be transmitted parenterally. In the case of Virus B, although Iablokowa,[5] Shank and Mirick as quoted by Aycock and Oren[6] and Bradley[7] have observed clinical situations which suggest the contact transmission of this infection, the parenteral route is the only one which has been demonstrated conclusively. There are certain clinical differences which

characterize the illness produced by the agents, which, while they may not be too helpful in making a differential diagnosis in individual cases, are nevertheless apparent when a large number of cases are studied. The incubation period for Virus A is usually in the range fifteen to forty days; while that for serum hepatitis is sixty to 160 days.[2] Onset is usually febrile and acute in the case of the former while it is usually insidious and afebrile in the case of the latter. There are also some suggestive differences in the changes noted in the liver function tests during the course of the illness. Some immunological differences have also been demonstrated. There is apparently no heterologous immunity between the two. Homologous immunity has been demonstrated in the case of Virus A[8] and this fact is put to good and practical advantage in the prophylactic use of gamma globulin. Attempts to show protection with gamma globulin prepared from the blood of convalescents from Virus B infection have failed.[9] However, the fact that not all persons who receive inoculations of icterogenic material develop hepatitis, while others who have had hepatitis may withstand homologous challenge, suggests that the actual situation here may not be simple.

The question of incubation period may be linked with immunological factors. MacCallum[3] has recently made a suggestion which could explain the apparently anomalous findings which have been reported where known icterogenic material may cause short incubation hepatitis in one recipient and long incubation hepatitis in another. As an example, if the donor's blood contained both Virus A and B, it would cause long incubation hepatitis in a person immune to A, short incubation hepatitis in a person immune to B and either short or long in a person with immunity to neither.

The long incubation period and apparent absence of antibodies in the case of Virus B infections have given rise to a great deal of speculation. A recent suggestion is that of Burnet[10] who considers the implications of transplacental transmission at a time when the embyro is unable to distinguish between what he terms "self" and "non-self" proteins.

Carriers undoubtedly constitute the primary source of infection for both Virus A and Virus B. The information available concerning carriers is far from adequate; but even so it is somewhat more extensive in the case of Virus B. It is widely recognized that cases of homologous serum hepatitis develop following the administration of blood from donors who were in good health at the time of collection of the blood

TABLE I.—RESULTS OF INOCULATION OF VOLUNTEERS WITH SERUM FROM SUSPECTED DONORS

Case	Donor	Days Since Incriminated Donation	No. Volunteers Inoc.	Cases of Hepatitis: Jaundice With	Jaundice Without	Total	Incubation Period (days): In Volunteers(c)	Original Recipient
1	W.C.	203	10	0	0	0	—	65
2	L.H.	385	10	4	2(a)	6	(18),30,45,46,(46),56	48
			5	0	1	1	(43)	
3	V.S.	356	10	1	0(a)	1	48	40
5	R.F.	149	10	1	0(a)	1	84	70
7	H.H.	135	10	4	0	4	35,50,56,72	
			5	5	—	5	43,49,56,57,63	44
8	C.D.	43	10	2	1(b)	3	(50),57,67	32

(a) One additional subject in each of these groups showed development of equivocal or abnormal hepatic tests suggestive of hepatitis without jaundice.
(b) Three additional subjects in each of these groups showed development of equivocal or abnormal hepatic tests suggestive of hepatitis without jaundice.
(c) Incubation periods in parenthesis refer to cases of hepatitis without jaundice.

Reprinted by permission, in modified form, from article by Murray et al.,[13] in *J. Amer. med. Assoc.* *154*:1072-74, 1954.

and had been screened with this possibility in mind. Stokes et al.[11] have produced evidence that there are carriers of both infectious hepatitis and serum hepatitis. In one of the instances cited, there was circumstantial evidence at least that a carrier of Virus B remained infective for as long as five years. Neefe et al.[12] studied a number of suspected carriers with a view to characterizing them from the point of view of their liver function. Inoculation of sera from six of these suspected carriers into volunteers by Murray et al.[13] clearly demonstrated that five of the six were in fact carriers. The results obtained in this study are summarized in Table I (taken from this paper) and illustrate a number of facts concerning the transmission of hepatitis.

1. Five of the six serums studied were icterogenic.
2. Two of these caused a relatively large number of cases among those inoculated, 7/15 (46.7 per cent) in one and 9/15 (60 per cent) in another.
3. Two resulted in single cases.
4. The incubation periods of the illnesses produced in the volunteers corresponded in general with those noted in the original recipients. It should be noted that many of these were shorter

than the usual 60-100 days given for Virus B. The reasons for these differences are not apparent. It is possible that strain differences may be operating, that the infectious titer may be the explanation or perhaps some unusual relationship between the infecting organism and antibodies to it. Since no information is available on these facts, it is idle to speculate upon them beyond mentioning the possibilities.

5. It was demonstrated that a carrier may be infective for as long as 385 days.

The fact that cases of hepatitis with relatively short incubation periods have been encountered in the case of carriers and are often seen after the administration of whole blood strongly suggests that some of the hepatitis transmitted by inoculation may in fact be infectious hepatitis (Virus A). The cases encountered following the administration of pooled plasma almost invariably have longer incubation periods. It has been suggested that one possible reason for this is the fact that antibodies for infectious hepatitis (Virus A) may be relatively common in the population and their presence in pooled plasma would tend to neutralize or modify any infectious hepatitis virus which may be present. The very excellent evidence that gamma globulin is effective in the prophylaxis of infectious hepatitis indicates that antibodies to this agent must be fairly common in our population.

No information is available concerning the number of individuals who may be carriers of Virus A. In the case of Virus B, it is possible to arrive at an indirect estimate by a review of transfusion records. The best estimate, based upon a review of the available literature, for the incidence of hepatitis following whole blood transfusions, uncomplicated by simultaneous administration of pooled plasma, is between 0.3 and 0.5 per cent. In trying to relate this estimate to the number of carriers involved we must consider two circumstances which tend to affect this figure in opposite ways: 1) The administration of whole blood is seldom restricted to single transfusions so that we should perhaps say 0.3 to 0.5 per cent of those who receive blood transfusions may develop hepatitis with the understanding that most recipients are given more than one unit of blood; 2) Only about one-half of those who receive icterogenic material develop hepatitis. We have noted above that our studies with carriers resulted in rates from 10 per cent to 60 per cent. A review of subjects who received the infected plasma which we used

in many of our studies on the safety of blood products[14,15] indicated that approximately 52 per cent developed hepatitis. Approximately 12 per cent of these cases were anicteric and would in all probability have been missed were it not for the close scrutiny which these subjects received. Evaluation of reported figures where multiple cases of hepatitis have resulted from the administration of a certain lot or batch of material has been difficult; adequate follow-up is in most cases next to impossible. A rate of 50 per cent appears to be realistic.

The potential infectivity of icterogenic material is high. A figure of 0.02 ml. has been quoted as being capable of transmitting infection.[2] Our own studies provide indirect information in this regard by which a figure may be deduced by considering the pool of infected plasma which was used in a great deal of this work.[15] The pool consisted of 130 liters of plasma and was prepared by the addition of approximately one liter of plasma or serum collected from subjects in the acute phase of their illness to the plasma drawn off from some 408 commercially obtained bleedings. It is possible that some of these may have been icterogenic themselves. The final pool proved to be icterogenic and capable of producing infection in a dose of 1.0×10^{-4} ml. If we take into account the expected occurrence of carriers, two of the 408 bloods mentioned above could have come from carriers. Two average donations would provide approximately 500 ml. of plasma so that the 130 liters probably contained approximately 1.5 liters of icterogenic plasma. In all probability the virus titer in each of the separate icterogenic materials added to the pool differed. However, we can say that the initial dilution was approximately 1/100 and with an infective dose of 1.0×10^{-4} ml. the average original icterogenic material had an infective dose of approx. 1.0×10^{-6} ml. and if the titer of the various component materials varied much, some may have had a smaller infective dose. A recent study by Drake et al.[16] showed infectivity with 1/40 x this amount or 4.0×10^{-5} ml. This represents a very small amount of blood or plasma. So small in fact that the amount remaining on an instrument even after vigorous washing and meticulous cleansing might be infective.

General Prevention and Control

In the case of infectious hepatitis, presumably spread by the fecal-oral route, control depends in the main upon breaking the cycle of transmission. This is difficult to accomplish with any degree of security in

the case of a disease where we cannot isolate the etiological agent. In general, the precautions to be taken are those which one would apply in the case of typhoid. Gamma globulin has been shown to be effective as a prophylactic and should be used in family and institution groups.

Prevention of Parenteral Transmission: There is ample evidence in the literature that parenteral transmission takes place. Aside from the well known examples of plasma, serum and blood transfusion as well as the experience with serum-stabilized yellow-fever vaccine in World War II,[17] cases of hepatitis have been reported following malaria therapy,[18, 19] in diabetic clinics,[20, 21] following arsenotherapy[22] and chrysotherapy,[7] following venipuncture and other blood-letting procedures as well as following immunization.[23] Inadvertent infections have been noted in laboratory technicians.[24-27] It has also been reported following dental procedures[28] and non-medical activities such as tattooing[29-32] and as occurring among drug addicts.[33, 34] A number of blood derivatives including plasma, fibrinogen,[35] thrombin[36, 37] and fraction IV[38] have been shown capable of transmitting hepatitis. Control measures should be directed towards:

1. Prevention of inadvertent transmission by inadequately sterilized instruments
2. Selection of blood donors
3. Sterilization of blood and blood products.

Sterilization of Instruments: It is important to use an effective means of sterilization. While some chemical agents may be effective there is little certain information about their action. There is no evidence that any of the commonly used antiseptics such as alcohol, ether, zephiran, etc. are capable of inactivating Virus B. Heat, applied either by boiling or by autoclaving, has proved effective in practice. The section of the Minimum Requirements of the National Institutes of Health for Citrated Whole Blood[39] dealing with the sterilization of instruments calls for boiling for thirty minutes or autoclaving at 121° C. (15 lbs. pressure) for twenty minutes. Sterilization should be preceded by thorough washing to prevent organic material coagulating or drying on the instrument surfaces and thus interfering with the sterilizing process. The report of the Expert Committee of the World Health Organization referred to above recommended hot air sterilization at 170° C. for thirty minutes if the sterilizer could be properly controlled but preferably 180° C. for one hour. Autoclaving was recommended but the conditions were not

specified. Boiling in water for at least ten minutes was considered acceptable. The information which we have concerning the thermal death point of the agent is rather limited. Gellis et al.[10] have demonstrated that a mixture consisting of 40 ml. of normal serum albumin and 10 ml. of proved icterogenic plasma which had been heated at 60° C. for ten hours failed to produce hepatitis in 10 ml. amounts when inoculated into five volunteers.

Portions of the plasma pool referred to above were subjected to controlled heating and icterogenic activity was still clearly present after four hours at 60° C.[14] Five of ten volunteers who received 1.0 ml. doses of such heated material developed hepatitis. The average incubation period was slightly longer than that of cases developing from unheated plasma indicating that there was perhaps some reduction in infectivity.

Heating at 60° C. for four hours represents rigorous treatment for any microorganism and the fact that the agent of serum hepatitis survived this temperature should be accepted as indicating caution about the manner in which instruments are sterilized.

More is needed than the actual process of sterilization in order to minimize the danger of parenteral transmission. Our mental approach to the subject is important. Although the simple matter of using a separately sterilized needle and syringe for venipunctures or parenteral inoculations would seem to solve part of the problem, there is considerable reluctance among many physicians to abandon the convenient but inadequate method of using separate needles with a single syringe and a number of ingenious devices have been invented to prevent back-flow and so permit the continued use of this procedure. In view of the demonstrated potentially high infectivity of some blood one must assume that the danger still exists. The increasing use of disposable single-use instruments is encouraging. Another possible source of danger is the multiple dose container, the contents or stopper of which may become contaminated if meticulous syringe procedures are not followed. Packages of biologics are now required to carry a warning statement in this respect.

Selection of Blood Donors: Present requirements for the screening of blood donors call for the elimination of donors with a history of hepatitis, donors with close contact during the preceding six months with individuals having viral hepatitis and donors who themselves received a blood or plasma transfusion during the preceding six months.

Obviously, these measures are not completely effective as cases of hepatitis still occur following blood transfusion. This circumstance does not appear to be a valid reason for abandoning these screening procedures, however. In examining the carriers discussed earlier, Neefe et al.[12] were impressed with the number of these individuals who had abnormal liver function tests, particularly abnormal thymol turbidity levels. The suggestion has been made that the institution of this test for screening might be helpful. A number of attempts have been made in this direction but no clear-cut indication of any advantage to the institution of this measure has as yet emerged. Contributing factors to this are: 1) Frequent occurrence of abnormal thymol turbidity levels in the presumably normal population, running as high as 15 per cent whereas the carriers probably do not exceed 0.5 per cent and we could only expect to exclude a fraction of these at best; 2) The fact that large numbers of bloods collected are chylous which in itself results in an elevation of the thymol turbidity in some instances; 3) The reluctance of those responsible for operating blood banks to accept a rejection rate as high as 15 per cent. The method is nevertheless worthy of serious consideration even if it is only partially effective as a means of excluding potential carriers.

Sterilization of Blood Products

Plasma Pool Size: Knowing that carriers do occur, and that approximately 0.5 per cent of those who receive whole blood collected from donors who have been adequately screened by present standards, indicates that the danger of infection from any pool of plasma prepared from such bloods depends, among other things, on the number of units entering into it. It is obvious that a "statistical" method of reducing the danger would be to reduce the number of units in each pool of plasma. The ultimate in this direction would, of course, be single donor plasma. This, however, presents an additional problem, namely that of cross matching before administration. It limits the usefulness of such a product under disaster conditions. A number of blood banks are, however, preparing plasma of this character. Difficulties related to cost, handling and bacterial contamination are increased by decreasing the size of the pools as far as the commercial production of plasma is concerned.

Ultraviolet Irradiation: Early hopes for the effectiveness of ultraviolet radiation as a method of eliminating or reducing the hazard of serum hepatitis, at least in the case of serum, led to its introduction as

a means of freeing plasma of the virus of serum hepatitis. A special feature of this method was that the plasma proteins appeared to be unaffected by the amount of ultraviolet energy used. A number of reports now indicate that cases are being encountered even with materials which it was believed had been rendered safe. A rate as high as 11.9 per cent was reported in one series of recipients who had been carefully followed for at least six months.[41]

Three studies on the effect of ultraviolet light were carried out by our group using material from the infected plasma pool which has been described.[15] The irradiators studied were (a) the Dill Irradiator, (b) the Habel-Sockrider Irradiator, and (c) the Oppenheimer-Levinson Centrifugal Filmer. In all instances particular attention was paid to the measurement of the U. V. output of the lamps used, to continuous monitoring of each irradiation run and to the accurate measurement of the rate of flow of the plasma through the apparatus. Cases of hepatitis occurred following inoculation into volunteers of all materials run at practical levels of irradiation, the exceptions being plasma which had been passed through the Habel-Sockrider apparatus five or more times, treatment which resulted in definitely detectable changes in the plasma proteins. The studies with the Dill Irradiator were performed first because this type of apparatus was most widely used. When sterilization of the infected plasma was not achieved even at 3 times the level of irradiation used commercially an attempt was made to verify, if possible, the results of the work of Blanchard et al.[42] with the identical apparatus used by these authors. The Oppenheimer-Levinson apparatus was studied because it possesses the feature of being able to present an extremely thin film of plasma for irradiation. These results were certainly most discouraging. Ultraviolet irradiation is a difficult process to apply with certainty and the above results may mainly reflect the inadequacy of design of the irradiators used. However, these were the only types available for commercial use at the time these studies were conducted.

A number of rather interesting and perhaps significant features were noted in examining the records of the individuals who developed hepatitis in the course of this particular study.

1. A lengthening of the incubation period.
2. A lessening in the severity of the illness encountered in terms of duration of illness (based upon abnormal laboratory findings)

and maximum total serum bilirubin levels reached during the course of the illness.

These findings strongly suggest that even though ultraviolet irradiation is not completely effective with the types of irradiating apparatus generally available, it must have some effect on the virus present. In addition, of course, it is an excellent means of destroying live bacteria and has a valuable function in this respect.

Room-Temperature Storage: Room-temperature storage of plasma has recently received considerable support as a means of reducing the hazard of hepatitis. This stems largely from the reports by Allen and his co-workers.[43] An attempt to determine the efficacy of this method was made, utilizing portions of the infected plasma pool which we have previously described.[44] One out of 19 volunteers who received plasma stored at 70° C. for six months developed hepatitis. This case was unusual because of the long incubation period, but the fact that it was possible to transmit hepatitis by means of blood taken from him in the acute phase indicates that this actually was a case of hepatitis. One must conclude from this that the infectivity of the plasma had been considerably reduced by storage for six months. The evaluation of the significance of the one case presents a problem. Had further cases occurred one could say with a fair degree of certainty that the material did contain the hepatitis virus. One case, however, does not constitute absolute proof of failure of inactivation. In the case of plasma stored for three months under the same conditions, three of five volunteers inoculated developed hepatitis; incubation periods were eighty-two, ninety-five and 117 days. This indicates that the agent we are dealing with is quite resistant to inactivation by this means. This method of inactivation may have limited applicability because of the hazard of bacterial contamination (psychrophilic organisms must be taken into consideration here)[45, 46] although Allen's own experience in this regard has been favorable. Furthermore, there is considerable alteration of the plasma proteins other than the albumin component.

Immune Serum Globulin: The Minimum Requirements of the National Institutes of Health for Immune Serum Globulin have in the past stipulated that pools consist of at least 500 individual contributions; present requirements call for 1,000. In view of the estimated number of blood donors who are carriers, it might be expected that many of the pools of plasma used in the manufacture of immune serum globulin

would be infected. General experience indicates that the incidence of homologous serum hepatitis following administration of immune serum globulin must be low. Cockburn[47] has reported the development of one case of hepatitis among fifty-eight subjects inoculated with immune serum globulin produced by ether fractionation. The plasma used in its preparation gave rise to seven cases of hepatitis among ten children who were given from 5 to 30 ml. parenterally.

Immune serum globulin was one of the products prepared from the infected pool plasma.[48] This was administered to ten volunteer subjects in 2.0 ml. doses. Simultaneously, five volunteers in a control group each received 1.0 ml. of the original plasma from which the globulin had been produced. None of the subjects who received globulin developed hepatitis, with or without jaundice, while one of the five in the control group developed hepatitis with jaundice having an incubation period of eighty-four days. A second individual in this control group developed positive hepatic tests suggestive of hepatitis without jaundice.

Thrombin: Some vials of thrombin from a commercial lot reported to have caused hepatitis in a number of patients who had received it as a topical application following surgery of various types were investigated. The results of these studies have been reported jointly by Dr. Stokes' group, Philadelphia, and ourselves.[37] The particular lot of thrombin studied proved to be icterogenic. Whether this represents a breaking through the manufacturing process by the virus is not clear. The possibility exists that it may have been introduced by the placental extract used to activate prothrombin to thrombin, a process carried out subsequent to alcohol fractionation.

Albumin: Paine and Janeway[49] after reviewing the records of 237 patients who received albumin intravenously concluded that their findings suggested that the use of human albumin intravenously does not carry the risk of homologous serum jaundice that exists with the use of pooled plasma or serum and to a lesser extent with single donation plasma or whole blood. The safety of albumin was strongly indicated by the studies of Gellis and his associates,[40] previously referred to in connection with the resistance of the agent to heat, and is borne out by studies (unpublished as yet) carried out by our group using albumin prepared from icterogenic plasma by alcohol fractionation followed by heating at 60° C. for ten hours, a required step in the processing of normal serum albumin (human).

TABLE II—EFFECT OF DIET ON DURATION OF ILLNESS

Infecting Material	*No. of subjects* *Special Diet*	*Ad lib Diet*	*Duration of Illness (days)** *Special Diet*	*Ad lib Diet*	*Statistical Evaluation of Differences*
Infected Pool Plasma	9	10	90	62	Significant
Infected Pool Plasma, treated	14	15	42	56	Not significant
Carrier Material	8	7	60	39	Not significant
Thrombin	1	3	....	....	
Statistical evaluation of differences			Signif.	Signif.	

* Time in days during which Total Serum Bilirubin (T.S.B.) remained above 1.0 mgm. per cent.

TREATMENT OF HEPATITIS

The results of studies on the effect of diet on the course of hepatitis in sixty-seven volunteers who participated in some of the above investigations have been reported by Leone et al.[50] Of these, thirty-two were in a "special" diet group and thirty-five in an "ad lib" diet group. The former received a diet consisting of 3844 calories (215.2 gm. protein, 79.2 gm. fat and 579.4 gm. carbohydrate) while the diet received by the latter group consisted of 2609 calories (93.8 gm. protein, 90.5 gm. fat and 361.7 gm. carbohydrate).

The cases of hepatitis studied resulted from parenteral inoculation of the following infecting materials which were being studied for the presence of the agent of hepatitis:

A. Infected pool plasma.

B. Infected pool plasma, treated. This represents materials which remained infective after various attempts at inactivation of the virus.

C. Carrier material.

D. Thrombin.

The distribution of the sixty-seven cases between the two diet groups, according to type of infecting material, is summarized in Table II.

The evaluation of the effect of the two diets was made chiefly in terms of the duration of illness of these cases.

The following main results were obtained:

With return to a bilirubin level of 1.0 mgm. per 100 ml. taken as the endpoint of recovery

(a) Subjects who received infected pool plasma and were given the "special" diet had a course of illness which was on the average 23 days longer than the corresponding individuals on the "ad lib" diet. This difference was statistically significant.

(b) Subjects who received infected pool plasma, treated, and were given the "special" diet had a course of illness which was on the average 14 days shorter than corresponding individuals on the "ad lib" diet. This difference did not reach statistical significance.

(c) Subjects who received "carrier material" and were given the "special" diet had a course of illness which was on the average 21 days longer than corresponding individuals on the "ad lib" diet. This difference was not statistically significant.

When the figures were examined to determine the role of the infecting material within each diet group, information of considerable interest emerged. Thus, in this series of cases and with the therapy used the type of inoculum received by the patients played a greater role in determining the course and outcome than did the therapy. Various other criteria for duration and severity of illness were examined with essentially the same findings. In most clinical situations little will be known concerning the nature of the infecting material but one can assume with some reason that there must be considerable heterogeneity as to source and amount of inoculum. A further observation made in the study was that the occurrence of complications was greater in the group which received the "special" diet. These findings indicate that the evaluation of any general type of therapy in the treatment of hepatitis must be approached with great care and planning; they also suggest that conclusions based upon a few cases must be accepted with reservation.

In another recently completed, carefully controlled study of the effects of bed rest and diet in the treatment of infectious hepatitis[31] no demonstrable preference was observed in favor of strict bed rest when compared with "ad lib" activity. A forced high-protein and fat diet had a slight, but statistically significant, favorable effect on the rate of convalescence. The apparent differences between these results and those reported above may have been due to (a) the fact that one group

consisted entirely of cases of homologous serum hepatitis[50] while the other consisted of cases of infectious hepatitis,[51] (b) the cases of serum hepatitis studied could be placed under treatment at a much earlier stage in the course of their illness than was possible in the latter study with cases of infectious hepatitis, and (c) the average severity of the illnesses encountered.

Medical emergencies arising in the course of hepatitis must, of course, be treated on an individual basis. Massive doses of cortisone have been suggested[52] as being life-saving in treatment and management of coma but the information available so far is too scanty to warrant any definite conclusions. The use of cortisone or ACTH[53, 54] apparently causes amelioration of symptoms in some cases as well as a return towards normal in the laboratory findings but presents difficulties in management with the danger of a relapse following withdrawal and there is no certainty that their effect on the total course of illness is appreciable.

Summary

The control of infectious diseases is extremely difficult when the etiological agent cannot be isolated. This is evident with both infectious hepatitis (virus A) and with serum hepatitis (virus B), although the information available concerning the transmission of the latter is more definite. Asymptomatic carriers have been shown to exist in the case of the latter and probably exist in the case of the former. Undoubtedly, they constitute the primary source of infection.

The control of infectious hepatitis rests on (a) the institution of general measures designed to break the cycle of a water-borne, food-borne or person-to-person transmission of infection, and on (b) the prophylactic use of gamma globulin.

In the case of serum hepatitis the control measures are more specifically directed to interrupting the transmission of the agent from person to person by inactivating or eliminating the agent from human blood and blood products used for therapeutic and diagnostic purposes and by preventing the transfer of contaminated blood by means of blood-letting and other instruments. Certainty in these methods of control is complicated by the high infectivity of some sera from individuals harboring the infection (approximately 1.0×10^{-6} ml.) and by the extreme resistance of the agent(s) to destruction by physical or chemical means.

Ultraviolet irradiation has been shown to be ineffective, at least as

performed on a production basis, at levels that do not alter plasma proteins. Room-temperature storage reduces infectivity but the method is not without limitations. The chemical agents which have been tried have been only partially effective. Fractionation by the cold ethanol method produces gamma globulin and albumin which are safe. The latter, however, must be heated at 60° C. for ten hours to eliminate the danger of the transmission of hepatitis. Fibrinogen and thrombin may both be icterogenic. Although careful screening of blood donors on the basis of history and liver function tests undoubtedly may contribute to the reduction of the number of icterogenic bloods which are collected, there is no method available for eliminating the danger from whole blood.

The treatment of uncomplicated hepatitis has depended chiefly on the institution of bed rest and the use of special diets; high-fat, low-fat, and high-protein diets have been recommended at various times. The extreme variability in the severity of the clinical course of hepatitis makes evaluation of any therapeutic measure difficult in the absence of extensive series of cases in which the effects of the therapy being studied have been thoroughly controlled. Recent attempts to evaluate diet and bed rest as therapeutic measures have shown that there may be some slight advantage to a high-protein diet in the case of infectious hepatitis while in the case of serum hepatitis such a diet appears to be without advantage and may actually be deleterious in some situations.

These measures of control and management are illustrated from the results of a series of studies conducted in human volunteers which had as their purpose the evaluation of the safety of blood and blood products with respect to serum hepatitis.

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EXHIBIT NO. 5

COMMITTEE ON MEDICOLEGAL PROBLEMS

The Committee on Medicolegal Problems of the American Medical Association has approved the publication of the following report prepared by Alexander S. Wiener, M.D., with the assistance of David N. W. Grant, M.D., Lester J. Unger, M.D., and William G. Workman, M.D.

J. W. Holloway Jr., *Secretary.*

MEDICOLEGAL ASPECTS OF BLOOD TRANSFUSION

During the past few decades vast strides have been made in the practice of blood and plasma transfusion. Blood transfusion has become a safer and less unpleasant procedure for the patient as a result of two advances: firstly, the discovery of the Rh factor, which led to new tests for the detection of intragroup incompatibilities, and secondly, the discovery of the cause of pyrogenic reactions and the development of methods of preventing them. The introduction of blood banking, which has been greatly expanded in recent years, thanks to the invention of inexpensive and reliable expendable transfusion equipment for the collection, storage and administration of blood, has greatly increased the ready availability of blood and plasma. Accordingly, today blood and plasma transfusions are almost as commonplace as ordinary sodium chloride and glucose infusions. This has made possible major surgical procedures previously too dangerous to undertake, and has also reduced markedly the frequency of deaths from hemorrhage.

Because of the ease with which transfusions can be carried out, there has been a tendency to overlook the fact that blood and plasma transfusions are attended with certain dangers which are not shared by simpler intravenous procedures. Recent reports[1] estimate the mortality from blood transfusion at the present time, even at the best-run institutions, to be approximately 1 death in 1,000 to 3,000 transfusions. Considering that as many as 3,500,000 transfusions may be given annually in this country,[2] this makes blood transfusion as important a cause of death as appendicitis or anesthesia. It is the ethical and legal responsibility of all physicians and hospitals to take every precaution possible to safeguard the patient against these dangers. The purpose of this report is to review the untoward sequelae which may follow blood and plasma transfusions, and the steps which can be taken to avoid these dangers. While the recommendations presented here are intended as a guide to physicians performing transfusions, allowance should be made for changes that may become necessary as new information becomes available.

HEMOLYTIC TRANSFUSION REACTIONS

One might imagine that at the present stage of knowledge hemolytic reactions caused by incorrect grouping of blood should no longer occur. However, there are circumstances under which errors may occur, namely, in times of unusual emergencies when incompletely trained individuals are called upon to perform such tests. This could occur not only in the event of national emergency, but also in peacetime. For example, when emergencies arise in the middle of the night or on holidays and the trained technician is not at hand, persons who have not been fully trained may be called upon to perform the grouping and cross-matching tests, and a certain number of errors are then inevitable. All hospitals should carry liability insurance. In addition, it is recommended that medical schools devote more attention to blood grouping in their curricula, so that interns and other young physicians who may be called upon to perform these tests in emergencies will be better equipped to do so.

A certain number of errors resulting from human fallibility are inevitable, but these should be kept at a minimum. Mistakes have resulted because blood grouping serums have inadvertently been interchanged; or when two patients have required transfusions at the same time, occasionally the bottles of blood intended for them have been interchanged. One of two patients with very similar or identical names may require a transfusion; in such cases also blood has been administered to the wrong person. In a few cases, errors have resulted because the wrong pilot tube was affixed to the bottle of blood. Most transfusions of blood of a wrong group can be traced to failure to read labels. A procedure should be set up in every hospital requiring that no technician may proceed with the blood grouping tests until he has read the labels on each bottle of grouping serums and every specimen of blood, and until he has established the identity of the patient receiving the blood. Colored grouping serums and labels have the disadvantage that the technician has a tendency to rely on his memory of the colors instead of reading the labels on the bottle of blood to be administered.

If a patient dies as a result of a transfusion of blood of an incorrect group, or suffers a prolonged illness due to injury to his kidneys, the patient's family or the patient himself, if he survives, may be entitled to damages unless there were extenuating circumstances calling for rapid action. Here the doctrine *res ipsa loquitur* may be applicable, because transfusion of an incompatible group at the present stage of knowledge may be considered prima facie evidence of negligence.

A-B-O Blood Groups.[3]—One of the commonest causes of hemolytic reactions is the transfusion of blood of an incompatible blood group. This may seem surprising considering that high-titered and specific blood grouping serums are now readily available, so that with care errors in blood grouping should hardly ever occur.* When carrying out blood grouping tests, it is important not only to test the patient's red blood cells with potent grouping serums anti-A and anti-B, but also to check the patient's plasma for its isoagglutinin content against known cells of group A and B.† While this check is not available when grouping blood from newborn babies, it is a valuable control on the results for older children and adults, and therefore should not be omitted. As an additional safeguard the bloods of donors and patients must be cross-matched by an acceptable technique.

No doubt, transfusion of blood of an incorrect blood group occurs far more often than the recorded instances. Natural anti-A and anti-B isoantibodies in human serums are generally of low titer and avidity, so that an initial transfusion of group A blood to a group O individual, for example, may be uneventful or give rise to a reaction from which the patient readily recovers. As a result of such a transfusion of incompatible blood the isoantibody titer will rise, so that if the error is repeated a fatal reaction could result. The titer and the avidity of the isoantibodies may be high, moreover, in individuals who have received previous transfusions of pooled human plasma or after heterospecific pregnancies, e. g., mother group O and baby group A, or after injections of horse serum or vaccines of bacteria grown on media containing peptone prepared with hog pepsin. In such instances, the very first transfusion of blood of an incompatible group may give rise to a severe hemolytic reaction, followed by anuria and death.

The severity of the reaction in strongly sensitized individuals depends on the amount of blood transfused, fatalities in adults being infrequent with quantities of blood less than 300 cc.

Because of lack of space, some of the bibliographic references have been omitted from The Journal and will appear in the committee's reprints.

Acknowledgment is made of the comments and suggestions received from the following consultants: S. T. Gibson, M.D., R. S. Muckenfuss, M.D., R. Murray, M.D., and I. B. Wexler, M.D.

1a. Moore, C. V.: Medical Problems Created by a National Blood Program, J. A. M. A. 149: 1613-1616 (Aug. 30) 1952.

1c. Straus, B., and Torres, J. M.: Use and Abuse of Blood Transfusion, J. A. M. A. 151: 699-701 (Feb. 28) 1953.

2. Dickinson, F. G., and Welker, E. L.: Survey of Blood Banks in the United States and Possessions: A Report to the Committee on Blood Banks, Bulletin 75, Chicago, American Medical Association, 1950.

3. Davidsohn, I.; Levine, P., and Wiener, A. S.: Medicolegal Application of Blood Grouping Tests, J. A. M. A. 148: 699-706 (June 14) 1952.

* Minimum requirements for blood grouping serum and anti-Rh typing serum are issued by the National Institutes of Health. Copies may be obtained upon application to the Laboratory of Biologics Control, National Institutes of Health, Bethesda 14, Md.

† The group A cells used should preferably be of subgroup A_1, in order to detect weak anti-A isoagglutinins.

Therefore, if the first portion of each unit of blood is given slowly and the patient watched closely during that time for untoward symptoms it may be possible to interrupt the transfusion in time, should a reaction develop. This safeguard is not available, of course, for patients under anesthesia. The increasing use of blood in the operating room for patients under anesthesia makes it necessary to emphasize one's complete dependence in such cases on the laboratory.

It has been claimed that the immediate symptoms of a hemolytic transfusion reaction may be suppressed while the patient is under cortisone or corticotropin (ACTH) therapy. However, hemolysis and hemoglobin nephrosis resulting in death is not prevented, so that such therapy does not eliminate the necessity for accurate grouping and cross-matching tests.

Subgroups of A.—It is important for the technician to be familiar with the subgroups of A in order to avoid errors in blood grouping. There are two principal forms of the agglutinogen A, namely, A_1 and A_2, the latter being characterized by its weaker reactions with anti-A serums. The reactions are especially weak in the presence of agglutinogen B, so that blood of subgroup A_2B (frequency of about 1.5%) has often been incorrectly classified as group B. (Bloods of subgroup A_3 and A_4, which are very rare, react even more weakly with anti-A serums.) The low avidity of most anti-A serums for A_2B blood which is responsible for errors in blood grouping also protects the patient receiving such incompatible blood from any dangerous reaction. That may be the reason why no serious transfusion reactions are known to have been traced to such a mistake in blood grouping. Nevertheless, in a well-regulated laboratory such errors should not occur. Although individuals of subgroup A_2 may occasionally have weak irregular isoagglutinins for subgroup A_1 and vice versa, no serious transfusion reaction has ever been traced to this source. For practical purposes, therefore, the subgroups of A are disregarded for blood transfusions, and donors are selected on the basis of the four blood groups.

Rh Factor.[3]—It has been found that it is not sufficient for recipient and donor to belong to the same A-B-O blood group, and today donors are routinely selected also on the basis of the Rh factor. Actually, the Rh-Hr types are quite complicated and reagents have been developed for as many as four different Rh factors and at least two Hr factors. For blood transfusion practice it is sufficient to limit the tests to only one of the Rh-Hr factors, namely, Rh_o,[4] the factor which corresponds to the one originally discovered with the aid of the anti-rhesus immune animal serums.

The Rh types differ from the A-B-O groups in that isoantibodies against the Rh-Hr factors do not occur in human serums except when induced by isosensitization. Therefore, generally, the initial transfusion of Rh-positive blood into an Rh-negative recipient is symptomless. In individuals who have been previously sensitized as a result of an injection of Rh-positive blood or a pregnancy with an Rh-positive fetus, even the first transfusion of Rh-positive blood can cause a severe reaction. The Rh_o factor is highly antigenic, so that about half of the Rh-negative individuals transfused with Rh-positive blood may become sensitized, and if the injections of Rh-positive blood are repeated over a long enough period of time eventually almost all Rh-negative persons may become sensitized. When isosensitization occurs in an Rh-negative woman this may prevent her from having a normal child, should her husband be Rh positive, especially if he is homozygous. That is another reason why Rh testing has become routine before blood transfusions, namely, not only to prevent hemolytic reactions but also to avoid the development of isosensitization which may cause erythroblastosis fetalis in subsequently born children.

The other Rh-Hr factors are much less antigenic than Rh_o, so that ordinarily they are disregarded when selecting donors for transfusion. By carrying out cross-matching tests by one of the modern techniques designed to detect "univalent" antibodies, e. g., the conglutination method, the anti-globulin method, or the test with enzyme-treated cells, incompatibilities with respect to the other factors of the Rh-Hr systems can be detected should isosensitization be present. Therefore, at least one of these tests should be included in the cross-match routine. While it is not essential, it is considered good practice to test all prospective Rh_o-negative donors further with anti-rh' and anti-rh" serums, and to consider only type rh blood (triple Rh negative) Rh negative for transfusion purposes, in order to avoid the possibility of sensitization against the factors rh' and rh". On the other hand, recipients belonging to type rh', rh", rh'rh", as well as type rh should be considered Rh negative, because blood of these types lacks the most antigenic Rh factor, Rh_o.

Potent and specific anti-Rh_o testing serums are commercially available, so that errors in Rh testing should rarely occur at the present time. Certain unusual blood specimens may offer difficulties in Rh testing, however, so that an accurate diagnosis can then be made only by a specialist. For example, variants of the Rh factors exist, of which the most important are the Rh_o variants ($\overline{Rh}_o$).‡ Persons with blood possessing an Rh_o variant may be incorrectly classified as Rh negative, unless special testing serums are available and special techniques such as the anti-globulin (Coombs') test are resorted to. Transfusion of blood containing an Rh_o variant into an Rh-negative recipient can give rise to isosensitization, just like typical Rh-positive blood. On the other hand, under certain conditions, Rh-negative blood may seem to react as Rh positive. For example, if bloods from pregnant women are tested by the slide technique, rouleaux formation which occurs in pregnancy may be mistaken for clumping. In acquired hemolytic anemia, the red blood cells may be coated with autoantibodies, which may be responsible for clumping in tests carried out by the conglutination method. Of course, these difficulties apply primarily to patients and not to healthy prospective donors. When the results of a slide Rh test are unclear, the test should be repeated by the tube agglutination method.

In most cases where Rh-positive blood is transfused to Rh-negative individuals, this can be traced to some error rather than a peculiarity in the blood to be tested. At the present stage of knowledge, if a hemolytic reaction occurs due to a transfusion of Rh-positive blood to an Rh-negative patient, it is generally prima facie evidence of negligence. The physician and hospital should make certain that all Rh-negative patients receive only Rh-negative blood, not only to prevent reactions, but also to avoid the development of isosensitization in women capable of child bearing. (This rule is not applicable in cases of dire emergencies, as is discussed later on.) Court actions have been initiated by women who had stillbirths which they traced to isosensitization produced by an earlier transfusion of Rh-positive blood.

Thus, the selection of donors for transfusion is no longer the simple procedure it was a few years ago. With the realization of the importance of the Rh-Hr factors, and the introduction of new complicated blood typing and cross-matching procedures, it has become necessary to relegate this work to specially trained individuals. Every blood bank and hospital where blood transfusions are carried out should have such specially trained technicians to handle this work under qualified medical supervision. Only in that way can maximum safety for the patient requiring blood transfusion therapy be obtained.

"Universal" Donors.—While transfusion of group A blood into a group O recipient may cause a serious reaction, the transfusion of group O blood into a group A recipient is generally harmless. The reason for this is that in the former case a relatively small volume of incompatible donor's cells combine with the isoantibodies present in a much larger volume of the recipient's plasma, while in the latter instance a limited amount of incompatible donor's plasma is diluted in the recipient's circulation and absorbed by the great mass of the patient's red blood cells. In general, therefore, blood containing incompatible agglutinins is much less dangerous than blood containing incompatible agglutinogens, and that is the basis for the use of group O individuals as so-called "universal" donors. The advantage of the use of universal donors is that by selecting such group O donors ahead of time by careful grouping tests done at leisure, time is saved in emergencies. This eliminates the danger of errors in blood grouping, which are particularly prone to occur when tests are carried out

‡ Rh_o variants have also been referred to by the symbol D^u.

hurriedly or by poorly trained technicians. For this reason in England at one time only volunteer donors of group O were used for blood transfusion. This policy was abandoned primarily because a shortage of blood was created by the failure to use donors belonging to the other blood groups, A, B, and AB.

It is now known, moreover, that transfusion of group O blood into individuals of other groups may occasionally be dangerous. Hemolysis may follow such transfusions when the donor has isoagglutinins of high titer in his serum. In a number of cases this has been traced to the use of donors who had recently received injections of tetanus antitoxin prepared in horses (cf. page 1435 under A-B-O Blood Groups).

While the injection of high-titered group O blood into individuals not belonging to group O may produce an acute hemolytic reaction, the symptoms are usually somewhat different from those which occur when incompatible red blood cells are injected. When potent incompatible antibodies are introduced they coat the recipient's red blood cells and an hemolytic process develops, which may continue over a period of days, producing a clinical picture resembling that of acquired hemolytic anemia. Therefore, it is preferable to transfuse only blood of the same group as the recipient whenever such group specific blood can be made available. The use of group O blood as "universal" donor blood should be restricted to emergencies where there is not enough time to determine the blood group of the recipient reliably. When more than a single unit of group O blood has to be administered to a patient not belonging to group O, one must bear in mind the possibility of a cumulative effect from the incompatible isoantibodies. Except under extraordinary emergencies, while the first unit is being administered there should be ample time to group the patient in order to select blood of the patient's own group, should additional transfusions be required.

To provide for emergencies the titer of the isoagglutinins in group O blood should be determined, and those units of group O blood with low titers may be marked for use as "safe" universal donor blood. The simplest method is to screen out those group O bloods with isoagglutinin titers which in the experience of the laboratory would be included among the highest 10 to 30%, and to use only the group O bloods with lower titers for this purpose. The value of the use of A and B blood group substances in this connection has not been clearly established. When an emergency makes the use of "universal" donor blood essential, a statement to this effect should be written on the hospital chart as a safeguard should a reaction result and a lawsuit be instituted.

In the case of emergency, of course, it is not feasible to carry out the delicate tests necessary to determine the Rh factor reliably. Routine Rh tests are usually performed during pregnancy on all obstetric cases, and the results of these tests can serve as a guide when selecting blood for such patients should an emergency arise during delivery. Where such information is not available and a dire emergency exists, preferably low-titered group O, Rh-negative blood should be used for transfusions, especially to women during the child-bearing period. If Rh-negative blood is not at hand, and the transfusion is deemed a life-saving procedure, Rh-positive blood may be used provided cross-matching tests show no incompatibility. Obviously, one must balance the danger of hemorrhage against the danger of isosensitization, and a suitable entry should be made on the patient's chart to justify the course of action taken.[5]

The transfusion of Rh-negative blood of the proper blood group into an Rh-positive recipient is almost always safe. The likelihood that such transfusions may give rise to sensitization to one of the Hr factors is so remote that for practical purposes this is generally disregarded. However, such instances, though rare, do occur, so that careful cross-matching tests must be done to detect incompatibilities aside from those due to the Rh_0 factor. Another source of danger is the possibility of introducing Rh-negative blood containing potent Rh antibodies into an Rh-positive recipient, thus causing an hemolytic process. Or the transfusion of such blood into an Rh-negative pregnant woman could passively sensitize her and in that way conceivably cause erythroblastosis in her baby. These dangers can readily be avoided by testing all Rh-negative donors for Rh antibodies, and eliminating those who are sensitized, though this has not yet become a regular routine at most blood banks.

Other Blood Groups.—The serums of certain rare individuals contain naturally occurring irregular isoantibodies for blood group factors other than A and B, e. g., anti-M, anti-P, and anti-Lewis. Such natural antibodies are generally of low titer and most active at low temperature, and therefore do not cause transfusion reactions.

On the other hand, as a result of isosensitization, immune antibodies to blood factors besides Rh-Hr may be formed, notably anti-M, anti-Keil and anti-Duffy. These immune isoantibodies can give rise to serious hemolytic reactions, but such instances are quite rare. By careful cross-matching tests, using appropriate special techniques, antibodies capable of causing a reaction can be detected, but the in vitro reactions are frequently very difficult to elicit. For example, the so-called Duffy factor can be demonstrated only by means of the antiglobulin technique. When a patient has had an unexplained hemolytic reaction not traceable to the A-B-O or Rh-Hr factors, his blood should be studied by a specialist in the field before additional transfusions are given. For this purpose there are certain blood grouping laboratories to which the blood can be sent; and, in fact, any of the workers in the field would welcome such specimens because they are valuable research material.

The committee does not believe that reactions caused by sensitization to one of the other blood factors can properly be a cause of action for a lawsuit, provided that the physician and hospital have exercised ordinary care to protect the welfare of the patient.

Damaged Blood.—If the blood used for transfusion has been damaged during storage, it may break down rapidly in the patient's circulation and give rise to a hemoglobin nephrosis. Blood should always be inspected carefully by a responsible person before being issued, and if hemolysis is detected should not be released.§ One should also bear in mind that red blood cells are sensitive to freezing and over-heating, so that contact with dry ice must be avoided, and no attempt should be made to warm blood prior to or during its administration. Blood that has been stored too long or improperly can also give rise to transfusion hemolysis. The expiration date of blood depends on the medium in which it is stored. The National Institutes of Health permit an expiration date of 21 days for blood stored in acid citrate dextrose solution.

Needless to say, blood should be kept cold from the moment it is collected until it is used. It should be stored in a refrigerator, set at 4 to 10 C (preferably 4 to 6 C). According to the requirements of the National Institutes of Health, the temperature must be recorded at least once a day. This is discussed again in connection with the problem of infected blood. If the blood is properly refrigerated during shipment, it can be safely shipped by plane to other parts of this country, or even across the ocean. Containers have been devised in which the blood can be packed and kept at the optimal low temperature during shipping.

TRANSMISSION OF DISEASE

A serious problem is the possibility of the transmission of disease from donor to recipient. (The reverse possibility, namely, the transmission of disease from recipient to donor prevails only when direct blood transfusions are given.) One of the most serious dangers at the present time is that of transmitting homologous serum hepatitis to the patient. This may occur once among 200 patients receiving transfusions,[1a] and may be responsible for the patient's death once among 6,000 transfusions.[1a] This danger is even greater following plasma transfusions.

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5. For a detailed description of an acceptable procedure for use in emergencies, see Civil Defense Technical Bulletin, TB-11-5, and TB-11-6, Federal Civil Defense Administration, November, 1952.

§ Adequate examination is not possible, once the blood has been agitated.

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Homologous Serum Hepatitis.—Attention was called to this entity during World War II as a result of the extensive use of pooled dried plasma when treating battle casualties. (Previously the disease had been observed as a complication following the injection of yellow fever vaccine, stabilized with human serum, and following the use of therapeutic immune human serums.) After an incubation period which may vary from one to six months, jaundice appeared in certain of the patients receiving plasma transfusions. Investigation revealed that in other patients receiving transfusions of the same lots of plasma jaundice also developed, confirming the suspicion that the plasma was the source of the hepatitis.

Plasma for transfusion is prepared in large pools in order to make safe its use in emergencies for individuals of any blood group. By pooling plasma of all blood groups, exceptionally potent isoagglutinins present in a particular sample of plasma are diluted, and at the same time plasma of opposite groups mutually inhibit one another's isoagglutinins by virtue of the soluble blood group substances which plasma contains. On the other hand, pooling increases the hazard of homologous serum hepatitis, because the presence of the virus in a single sample of plasma will serve to contaminate the entire pool. Thus, a pool of 50 units of plasma would be about 50 times as likely to transmit the disease. Indeed it has been found that homologous serum hepatitis occurs in as many as 12% or more of patients receiving pooled dried plasma, as compared with an incidence of 1 in about 200 after transfusions of whole blood.

For the purpose of this discussion, the most important difference between homologous serum hepatitis and infectious hepatitis (catarrhal jaundice) is the mode of transmission. Unfortunately, there is no simple test by which a carrier of the virus can be recognized, and the presence of the virus in a plasma pool can be detected only by testing it on human volunteers. The use of surplus plasma in civilian practice after the war resulted in additional instances of homologous serum hepatitis. Since the plasma in these instances had to be used in emergencies to save lives when blood was not available, at least one court has held that homologous serum hepatitis after plasma transfusions is a calculated risk, and no damages were awarded.[6]

Experiments have been carried out which suggest that ultraviolet radiation destroys the virus of hepatitis. Following this work, the National Institutes of Health have required that pooled plasma must be irradiated before distribution, and this ruling is still in effect. More recent observations indicate that such irradiation may not always be effective. Irradiation is not applicable to whole blood. One should also bear in mind the hazard of hepatitis to donors and patients from contaminated lancets and needles, and to workers handling human blood and plasma.

Summarizing the available data, one must conclude that the problem of homologous serum hepatitis has not yet been solved. The danger is much greater when pooled plasma is used than when plasma or whole blood derived from a single individual is administered. There is no practicable test to detect carriers of the virus, and the ability to transmit the virus may be retained for an indefinite period of time. Individuals with a history of hepatitis should never be used as donors for blood transfusion,[7] while individuals who have been intimately exposed to the disease should not be used as donors for at least six months. Such blood may be used for preparing plasma or plasma fractions, where adequate means for destroying the virus are used. When fresh, frozen, or freeze-dried plasma is needed, this should preferably be prepared from blood from a single individual, unless pooling is unavoidable. Thus, at the present stage of knowledge, homologous serum hepatitis is a calculated risk which the patient assumes as part of a blood or plasma transfusion.

7. Unfortunately, dangerous carriers of the hepatitis virus exist who give no history of hepatitis. (Oliphant, J. W.; Murray, R., and Neefe, J.: to be published; Stokes, J., Jr., and others; to be published.)

Syphilis.—Transmission of syphilis by transfusion is rarely heard of any longer. This is mainly due to the development of more sensitive tests for the detection of the disease in prospective donors, while another effective factor in preventing transmission of the disease is the widespread use of bank blood. Since the agent of this disease cannot live more than a few days outside the body, even at refrigerator temperature, the danger of transmitting syphilis is virtually nonexistent when blood or plasma aged for at least three days is used for transfusions. No individual with positive serologic tests for syphilis or a positive history of the disease should be used as a donor for fresh whole blood. In emergencies, when the necessary serologic tests cannot be carried out, a note to that effect should be entered on the patient's chart in order to protect the physician.

Malaria.—Transmission of malaria by transfusion is a difficult problem in regions where the disease is endemic, but until recently was not an important problem in the United States. It is a possibility which one must bear in mind now that there are so many veterans of World War II and Korea who have returned from regions where malaria is endemic, and who have become prospective blood donors. Instances have been observed where malaria (notably Plasmodium malariae) was transmitted by blood donors who had had the disease more than 30 years previously. For obtaining fresh blood for transfusion, individuals who have had malaria or who have received suppressive therapy for malaria while residing in a malarious region should not be used as donors for a period of at least two years following the last proved attack or discontinuance of suppressive therapy.[8] Obviously, malaria cannot be transmitted by plasma which is free of cells. The P. malariae can survive in the refrigerator for as long as five days, so that bank blood less than five days old may be infectious. In regions where malaria is endemic, so that the use of donors who have had the disease is unavoidable, one can take advantage of the fact that the plasmodium dies after prolonged storage. In unusual emergencies, where possible malarial carriers must be used as donors for fresh blood transfusions, antimalarial therapy should be given to the recipient.

Other Infectious Diseases.—Other infectious diseases such as measles and influenza have been transmitted by blood transfusion. This has occurred when the donor was in the prodromal stage of the disease when his blood was used for transfusion. Needless to say, all prospective donors should be examined in order to detect the presence of infectious disease. In emergencies where no other donor is available, donors with mild upper respiratory infections may be used. Mild chronic infections such as sinusitis, mild acne, and mild pyorrhea generally are not considered sufficient to exclude an individual from being a blood donor. No absolute set of rules can be drawn up to cover every conceivable situation with which the examining physician may be confronted, and the physician is therefore expected to use his best judgment before deciding to use any individual as a blood donor.

Contaminated Blood.—A difficult problem which has arisen as a result of the widespread adoption of bank blood is the danger of transfusing contaminated blood. Reports have appeared in the literature from time to time of deaths following such transfusions, and this is one of the most serious limitations to the use of stored blood.[9]

When fresh citrated blood was used exclusively for transfusion, open techniques for collecting the blood were prevalent, and it was only the introduction of blood banks that made the adoption of closed techniques imperative. As blood and plasma age they may lose their bacteriostatic and bactericidal properties due to the loss of complement and leukocytes, and aged plasma or blood is an excellent culture medium for bacteria. When blood is collected, even using the most rigorous aseptic techniques, it is unavoidable that occasionally some bacteria will be picked up from the deeper layers of the skin. Some of these organisms die or at least are prevented from multiplying

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while the blood is still fresh, and the low temperature at which blood is stored will tend to prevent the growth of the majority of bacterial contaminants later on. Unfortunately there are some bacteria which multiply readily at refrigerator temperature,[10] and whose presence may not be detected because they fail to hemolyze blood. The bacteria that have heavily contaminated blood, transfusion of which has been followed by shock and death[11] generally have been either of the genus Pseudomonas or of the coli-aerogenes group. In the latter group Escherichia freundii and Paracolobactrum aerogenoides appear to be the most important.[10]

Bacteriological surveys[12] have shown that as many as 5 to 10% of specimens of bank blood are contaminated with bacteria. Most transfusions of such blood cause no harm because the majority of the micro-organisms present are gram-positive bacteria which are relatively low in pyrogenicity, do not grow at refrigerator temperature, and are generally nonpathogenic. Routine bacteriological control of bank blood is not practicable, because the blood will age further while the cultures are being made, and the very act of obtaining a specimen of blood for the bacteriological examination may serve to contaminate the blood. Various antiseptics and antibiotics have been tried to inhibit the growth of bacteria in stored blood and plasma, but nontoxic quantities of such chemicals have proved ineffectual for checking the growth of bacteria.[13] At the present time it is not considered advisable to add any antiseptic to blood in an attempt to prevent bacterial growth, and prime reliance must be placed on stringent aseptic technique when collecting and storing the blood.

According to the requirements of the National Institutes of Health, it is not permissible to enter a bottle of bank blood to obtain a sample at any time before the blood is to be administered. The obvious purpose of this rule is to avoid contaminating the blood. Therefore, the grouping and cross-matching tests are generally carried out with the sample of blood in the pilot tube. However, there is no real objection to entering the bottle itself, provided the blood is to be administered no more than a few hours thereafter. If the bottle of blood is entered and the blood is not transfused immediately, it should not subsequently be used for transfusion as whole blood. A competent worker should inspect every bottle of blood in the blood bank daily for evidence of hemolysis, which can be detected as a zone of hemoglobin diffusing upward from the layer of sedimented cells. In rare cases of doubt, a sample of blood may be drawn from the bottle, inverted, and centrifuged, and then any hemolysis which may have occurred will be plainly visible as a discoloration of the supernatant plasma.

Summarizing, the problem of bacterial contamination when stored blood is used for transfusion has not been completely solved at the present time. The use of closed aseptic techniques for collecting blood and careful control of the temperature during storage reduce the chance of contamination and bacterial multiplication. Despite impeccable technique a certain amount of contamination is inevitable. In order to limit the growth of bacteria, the period of storage of blood should be made as short as possible and certainly not permitted to exceed three weeks, in conformity with the requirements of the National Institutes of Health. The addition of bactericidal or bacteriostatic chemicals to stored blood is not recommended.

OTHER ACCIDENTS FOLLOWING TRANSFUSION

Embolism.—During storage of blood or plasma, precipitation of fibrin gradually occurs, and if such blood or plasma is transfused unfiltered, multiple embolization into the lung bed may occur, or, if the recipient has a cardiac septal defect, into the viscera or brain. The older literature contains reports of sudden death following transfusions of such unfiltered plasma or blood, which probably can be explained on this basis. Therefore, bank blood and stored plasma should always be filtered during transfusion, and in fact commercial transfusion apparatus are available which have suitable filters in the drip chamber for this purpose.

Rapid transfusion of blood by pumping air under pressure into the blood reservoir has caused a number of deaths from air embolism. Such accidents are inevitable when this method is used, unless a qualified transfusionist is constantly in attendance and vigilant during the procedure, in order to terminate it before air has a chance to enter the vein. Since the method is not foolproof, transfusion of blood under air pressure is to be condemned. If blood must be transfused rapidly, it is a simple matter to insert a two way stopcock between the needle in the patient's vein and the infusion tubing, and to pump the blood in by syringe. The rate of the flow can also be increased by inserting a larger needle into the vein and raising the blood reservoir, or by setting up multiple blood infusions into both arms and legs of the recipient. The collection of blood in plastic bags also makes possible rapid administration under pressure without the danger of air embolism. The transfusionist must bear in mind that air embolism as the cause of a recipient's death may be considered prima facie evidence of negligence.

The local injury produced by the needle in the patient's vein may cause a thrombophlebitis with secondary embolism. Since the chance of phlebitis developing is directly related to the length of time the needle remains in the vein, the infusion should not be unnecessarily prolonged. Moreover, transfusion by improving the patient's circulation may be indirectly responsible for embolism from the site of an operation or an occult phlebothrombosis in the veins of the calves of bedridden patients. The rare accidents of this type are hardly ever predictable.

Thrombophlebitis.—Transfusions are given by entering an accessible vein through the skin with a suitable intravenous needle. At the termination of the transfusion the needle is withdrawn and a sterile compress applied to the puncture site, and only very rarely does any local infection or thrombosis of the vein result. Should blood infiltrate the tissues around the vein, it is usually absorbed without any serious local reaction. In emergencies, when the patient is in collapse from hemorrhage, it may be necessary to cut down on a vein and there may not be enough time to take complete aseptic precautions. In such situations, local infection and thrombophlebitis may result, and therefore adequate doses of an appropriate antibiotic or chemotherapeutic agent should be administered prophylactically.

Allergic Reactions.—About 1% of blood transfusions are followed by reactions of an allergic type. As a rule these reactions are mild and consist merely of the appearance of urticaria. Such a mild reaction does not make necessary the interruption of the blood transfusion, and if the itching is troublesome, 2 or 3 minims of 1:1,000 epinephrine may be administered subcutaneously. Angioneurotic edema is a more serious allergic manifestation which may be dangerous if it involves the larynx. Rarely, the recipient may exhibit asthmatic breathing after a transfusion. Should any recipient begin to wheeze or exhibit signs of angioneurotic edema, the transfusion must be discontinued at once, and small doses of epinephrine administered until the symptoms abate.

Allergic manifestations may be due to the presence in the donor's plasma of some food protein or drug to which the recipient is sensitized. Therefore, whenever possible only fasting donors should be used for blood transfusions to allergic recipients or for the preparation of blood plasma. On the other

10. Pittman, M.: Psychrophilic and Other Bacterial Contaminants from Human Blood and Plasma, read at the Proceedings of the Fifth Annual Meeting of the American Association of Blood Banks, Milwaukee, Oct. 9-11, 1952.

11. Borden, C. W., and Hall, W. H.: Fatal Transfusion Reactions from Massive Bacterial Contamination of Blood, New England J. Med. 245: 760-765 (Nov. 15) 1951.

12. Braude, A. I.; Sanford, J. P.; Bartlett, J. E., and Mallery, O. T., Jr.: Effects and Clinical Significance of Bacterial Contaminants in Transfused Blood, J. Lab. & Clin. Med. 39: 902-916 (June) 1952.

13. Swedberg, B.; Widström, G., and Alin, K.: Importance of Aseptic Technique and Fallaciousness of Chemical Bacteriostatics in Blood Banking and Plasma Preserving, Acta med. Scandinav. 127: 480-493, 1947.

197a — Exhibit No. 5

hand, inverse allergic reactions may result from the passive transfer of reagins from donor to patient. Such reactions may be immediate if the corresponding antigen is present in the recipient's body, or it may be delayed for days, depending on the next exposure to the antigen. Therefore, it is best not to use allergic individuals as blood donors. When no other donors are available, however, individuals with seasonal hay fever may be used at times of the year when the pollen to which they are sensitized is not prevalent.

Patients receiving repeated blood transfusions occasionally become sensitized to some ingredient of the plasma, and then exhibit chills and fever with each transfusion. By giving such individuals merely the washed red blood cells of the donor the chance of such reactions is reduced. Occasionally allergic reactions have been traced to sensitivity to some constituent of rubber tubing.[1] They are avoided by using plastic tubing.

Summarizing, allergic reactions following transfusion are hardly ever serious, and the occurrence of such reactions after approximately 1% of transfusions is to be expected. As a rule, allergic reactions do not interfere with the transfusion.

Pyrogenic Reactions.—In the past pyrogenic reactions were not only a nuisance, but in severely debilitated patients occasionally precipitated death from cardiac failure. The cause of such reactions has been traced to the growth of bacteria in the water used for preparing solutions, or in moisture adherent to the apparatus, before they are sterilized. Methods have been developed for preparing pyrogen-free solutions and apparatus, which are readily available commercially. Accordingly, pyrogenic reactions are no longer an important problem, and one should not accept such reactions as inevitable after intravenous infusions.

Overloading.—Too rapid transfusion or the transfusion of too much blood may cause deaths from congestive cardiac failure or cerebral hemorrhage. At one time, when it was customary to transfuse unmodified blood by syringe-valve apparatus, it was necessary to pump the blood in rapidly in order to avoid coagulation in the transfusion apparatus. By this technique occasionally distention of the neck veins was present at the termination of the transfusion, and certain instances of sudden death following transfusion were undoubtedly due to the too rapid injection of blood. The demonstration that sodium citrate is an innocuous anticoagulant converted transfusion from a spectacular procedure into a simple one deliberately performed, and increased its safety for the recipient. Unfortunately, a certain number of deaths from too rapid transfusion still occur, especially when transfusions are given to infants. Because of the technical difficulty of transfusing infants, there is a tendency to give too much blood and too rapidly. The danger of transfusing infants will be considerably reduced if this procedure is carried out only by experienced transfusionists, who are familiar with the problem of dosage and rate of transfusion.

Citrate Reactions.—The sodium citrate which is introduced during transfusion is rapidly metabolized and excreted. Therefore, the amount of citrate administered with 500 cc. of blood is harmless to the adult. However, when massive transfusions are given in a short period of time sodium citrate may accumulate in the blood stream, so that signs of hypocalcemia may result, namely, a drop in blood pressure and tetany. This possibility should be borne in mind when adults with massive hemorrhage require more than a liter of blood. If the practice is followed to inject slowly into the recipient's vein 10 cc. of a 10% solution of calcium gluconate after every 1,000 cc. of citrated blood, hypocalcemia can be prevented. Similarly when performing exchange transfusions on erythroblastotic babies, some transfusionists inject 1 cc. of 10% calcium gluconate after every 100 cc. of citrated blood; others meet the problem by removing part of the citrated plasma from the blood to be used for the transfusion.

Intra-Arterial Transfusion.—For obvious reasons, transfusions are almost invariably given into one of the veins. From time to time, the use of the intra-arterial route has been proposed for blood transfusion. Recently intra-arterial transfusion has again been advocated particularly for patients in deep shock from hemorrhage, who have failed to respond to intravenous transfusions. Such emergencies arise occasionally in the operating room after massive hemorrhages, such as may occur in the course of an operation on the lungs or heart. It has been claimed that introduction of blood into the circulation through an artery (usually the radial artery is used) under pressure causes the blood to enter the aorta directly, thus producing an immediate rise in blood pressure. Actually, the published experimental and clinical observations on intra-arterial transfusion have not supported its supposed theoretical advantages.[14] In addition, the method has the disadvantage that it is necessary to cut down on an artery, and after the transfusion the artery may thrombose and gangrene result. In view of the debatable status of the procedure, intra-arterial transfusions must still be considered an experimental procedure to be resorted to only in unusual cases of emergency.

Intramedullary Transfusion.—Many investigations have been carried out on the use of the intramedullary route for infusions, and numerous blood and plasma transfusions have been given successfully through the bone marrow. In adults generally the infusion is given through the sternal marrow, while in infants and small children where the sternum is too thin the tibial route is used. In general, the intramedullary route for ordinary transfusions is not recommended because of the danger of fat embolism, and, especially in children, the procedure has resulted in osteomyelitis and fractures of the tibia. The need for the intramedullary route in pediatric practice is avoided when trained individuals are available, who are skilled at intravenous procedures. In infants, scalp veins are generally available, and surprisingly large veins can frequently be found on the back of the hand, in the bend of the elbow, or at the ankle. If necessary, a cutdown can be carried out, and a vein can always be found anterior and superior to the medial malleolus at the ankle. Intramedullary transfusion has its main application in instances of extensive burns or patients with skin diseases which make intravenous therapy difficult. In such cases, the intramedullary routes offer a ready solution, and the method has proved particularly valuable in civilian catastrophies and in military medicine.

Other Routes.—Transfusion into the longitudinal sinus is dangerous because of the possibility that blood may be injected extradurally. Nobody any longer advocates the use of the intraperitoneal or penile routes.

PROTECTION OF THE BLOOD DONOR

At one time it was difficult to convince individuals to donate their blood for transfusion purposes. Experience during World War II has educated the public regarding blood transfusion, and demonstrated the relative harmlessness of being a blood donor. By the time the Red Cross Program was completed at the end of World War II as many as 13 million pints of blood had been donated,[15] and at the present time blood continues to be collected for civilian and military purposes at the rate of millions of pints per year. However, if adequate precautions are not taken to safeguard the welfare of the blood donor, his health may be jeopardized or even his life.

Secondary Anemia.—The most obvious danger of repeated blood donations is the development of secondary anemia. This danger is greater for women because of their smaller body size and blood volume, and because in addition they are subjected to periodic physiological blood losses. Therefore, women should donate blood at less frequent intervals than men. It is now a general policy not to permit donors to donate a pint of blood oftener than every 10 to 13 weeks, or until such time as the blood attains a hemoglobin concentration of at least 12.5 gm. per 100 cc.; or a specific gravity of 1.053 or higher. When donors take iron by mouth blood regeneration occurs more rapidly.

In this connection, the needle used for puncturing the finger to obtain blood for the hemoglobin concentration should be sterile in order to avoid the possibility of transmitting the hepatitis virus. Either individual expendable lancets should be used for this purpose, or individual lancets which have been

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1 New rubber tubing must be specially treated in order to avoid toxic reactions of a nonspecific nature.

13. American Red Cross Blood Donor Service During World War II: Its Organization and Operation: ARC 1267, Washington, D. C., American National Red Cross, 1946.

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subjected to sterilization procedures which have been shown to be capable of destroying the virus. Merely wiping the lancet with alcohol or immersing it in an antiseptic solution is not adequate. Sterilization for a sufficient length of time by dry heat, boiling or autoclaving will destroy the hepatitis virus.

Fainting.—The most disturbing accident occurring after a blood donation is faintness, or actual fainting, and occasionally deep unconsciousness. In this emotional factors play a certain role, because in some cases donors have fainted before they were bled, or the wife or husband fainted when the other marital partner was bled. Aside from the psychic aspect, the precipitating cause of fainting is the sudden reduction in blood volume. The incidence of fainting has been reported as varying between 1 and 6%; some persons are more predisposed to faint than others, and there is also a greater tendency to faint among donors of smaller size and lower blood volume. To counteract this tendency some transfusionists make a practice of taking smaller amounts of blood from such donors.

Probably one of the most important precautions is the proper care of the donor before the donation. The incidence of fainting can be reduced by screening out unsuitable donors by physical examination in order to exclude those with low blood pressure or a low hemoglobin level, or with small body size. Experience of blood banks shows that it is necessary to reject 10 to 15 times as many female donors as male donors. According to certain workers, when great care is taken to screen donors, the percentage of rejections may be as high as 28%.

A donor who has been without food for a long time or who makes his donation after coming off a night shift may be a candidate for fainting. Under these circumstances, a light snack immediately before drawing the blood will not spoil the plasma and may help to prevent unpleasant reactions. After the donation the donor should be kept in a supine position until he has apparently recovered. The nervous donor should be made to feel at home, and his attention should be diverted from the procedure by conversation about pleasant matters. The bleeding room should be light and airy, and smoking should not be permitted in it or in the resuscitation room. It has been demonstrated that the fainting rate can be reduced in donors from hot work-shops if they drink some isotonic sodium chloride solution before the bleeding, and certainly on hot days a glassful of water is a beneficial preparatory measure. If fainting or loss of consciousness should occur, it is handled by holding the head low, loosening the clothes and providing fresh air. Occasionally, intravenous infusions of sodium chloride solution may be required, and in very rare instances the donor's own blood may have to be restored to him. If it appears advisable, the donor may be kept in the hospital overnight. When such a donor has fully recovered it may be wise to send him home by car or with an escort.

More serious than fainting immediately after the donation is the occasional occurrence of syncope after the donor has left the hospital. The donor may fall and lacerate his scalp or even fracture his skull, or if he falls in the street in the midst of traffic or at work in a factory he may become involved in a serious accident. Therefore, donors involved in hazardous occupations should be advised not to return to work for at least 12 hours.

Thrombosis and Infections.—Needless to say stringent precautions must be taken to prevent infection of the puncture in the donor's arm. Although a certain percentage of hematomas is inevitable, especially when difficulty is encountered in entering the vein, such hematomas almost invariably disappear without sequelae. In very rare instances, thrombophlebitis or abscess formation has occurred at the site of the puncture, and at least one lawsuit against a blood bank has resulted. While the tendency of the court has been to favor the blood bank, provided there was no evidence of negligence in the performance of the phlebotomy or in the aftercare of the donor, it is wise for the blood bank and physician to protect themselves by suitable insurance.

In conclusion, one may state that the donation of a pint of blood by a healthy adult is safe. Among the 13 million donations during the war, there was only a single reported fatality caused by a sudden attack of coronary occlusion, and 10 additional fatal cardiovascular accidents which occurred 3 to 48 hours after the donor left for home. These few severe cardiovascular accidents are certainly no more frequent in number than would be expected among several million persons no matter what they did before death.

PREPARATION OF BLOOD DIAGNOSTIC SERUMS

Reliable blood grouping tests are possible only when potent and specific diagnostic serums are available. Therefore, the preparation of blood diagnostic serums is an essential aspect of the practice of blood transfusion. At one time anti-A and anti-B serums were obtained from random group B and group A individuals, respectively; similarly, anti-Rh serums were procured from Rh-negative individuals accidentally sensitized by blood transfusion or pregnancy. However, such antiserums selected at random are frequently of low titer and avidity, so that the use of such reagents has caused errors in blood grouping. Potent and specific antiserums can be obtained most consistently by deliberate immunization. For this purpose, experimental animals have yielded unsatisfactory results, so that human subjects have to be used for the preparation of diagnostic serums.

Immunizing and bleeding donors for the purpose of preparing blood diagnostic serums carries no hazard other than those associated with the blood donation and transfusion. In fact, though thousands of individuals have been immunized and bled for this purpose to date, no harmful effects from the procedure have ever been reported. At least one insurance company has permitted physicians of New York City doing this essential type of work to have a rider placed on their malpractice insurance policies to protect them against possible claims. While it has not been necessary to take advantage of this rider so far the practice should be adopted throughout the country in order to encourage the preparation of potent serums essential for safe transfusion practice.

Men are used more often than women for the preparation of diagnostic serums. Obviously no Rh-negative woman should be immunized with Rh-positive blood to prepare anti-Rh serums if there is any chance of her becoming pregnant later on. Similarly immunization of a group A woman against agglutinogen B or vice versa could conceivably cause obstetric complications. This limitation does not apply, of course, to women who are not capable of bearing children.

While the commoner serums, anti-A, anti-B, and anti-Rh$_o$, can be prepared by deliberate immunization of male volunteers, this technique is not readily applicable to weaker antigens such as rh', rh", hr', hr", Kell, and Duffy. To obtain these rarer reagents, one must depend principally on unusual clinical cases of erythroblastosis or hemolytic transfusion reactions caused by sensitization to these blood factors. The cooperation of physicians treating such patients, whether male or female, is therefore needed, so that some of their blood can be obtained for the preparation of diagnostic serums. Large amounts of blood may be withdrawn even from anemic individuals, provided that it is replaced by transfusions of carefully selected blood.

For preparing anti-A and anti-B serums, a number of different immunization procedures have been used successfully. The intravenous injection of blood group substances prepared from horse and pig stomach carries the possibility of anaphylactoid reactions in allergic subjects. This danger is avoided by using deproteinized preparations, such as are commercially available, and by administering them intramuscularly instead of intravenously. No serious reaction has been observed following such injections. For the preparation of anti-Rh serums, human blood must be injected intravenously; some workers use human blood also to prepare anti-A and anti-B serums. Because of the small volume of blood injected, the amount of intravascular hemolysis is negligible. Nevertheless, some subjects have complained of pain along the course of the vein during the injection, or have had a mild rise in temperature later on. The former can be avoided by diluting the blood with sodium chloride and injecting it more slowly; the latter by having the donor take 5 grains (0.32 gm.) of acetylsalicylic acid at the time of the injection or by reducing the dosage. Any injection of human blood carries with it the theoretical danger of homologous serum hepatitis. Against this eventuality

the same precautions should be taken as with the selection of a donor for blood transfusion.

Needless to state, before injecting blood or blood group substances into any volunteer, one must explain the purpose of the injection to him and make a full disclosure of the facts. At the same time one should point out the harmlessness of the injections as far as the subject's health is concerned. The sensitized Rh-negative donor could be given a suitable identification card, and warned that only Rh-negative blood be used for any transfusion he may require in the future, e. g., after an accident or operation. A signed release should be obtained from the donor, although such a release may not in all cases constitute a bar to a lawsuit.

In a few instances, volunteers immunized against the Rh factor have developed antibodies against other antigens, most frequently agglutinogen M. This can be avoided by testing all subjects for the M-N types, and using only type N, Rh-positive blood for Rh-negative donors of type N. Should sensitization to agglutinogen M as well as Rh occur, this is no serious matter, and if for subsequent injections only type N blood is used, the immune anti-M agglutinins soon disappear. Should an exchange transfusion be undertaken on such a subject, the antibodies for M as well as Rh must be taken into account in order to avoid a hemolytic reaction. As an additional precaution, exchange transfusion on immunized donors might be preceded by a biological test, namely a test injection of a small amount of the blood to be used for the transfusion.

Summarizing, human subjects are necessary for the preparation of high quality diagnostic serums essential for safe blood transfusion practice. The same high standards applied to ordinary blood donors and recipients should be used when handling such volunteers. Physicians are urged to enlist the cooperation of patients whose plasma contains rare blood group antibodies, so that their blood can be used for the preparation of diagnostic serums. Insurance companies specializing in malpractice insurance can aid the work by providing riders on policies of physicians specializing in this field.

QUALIFICATIONS OF TRANSFUSIONISTS

The administration of blood and plasma nowadays is mostly delegated to residents or physicians not specializing in this field. In general, such physicians are fully qualified to carry out blood or plasma transfusions, which in the average case offer no unusual difficulty. Situations arise, however, in which transfusions can be performed only by specially trained physicians, namely, on patients in deep shock with collapsed veins, and infants and children or other individuals with poorly developed veins. In addition, problems arise when atypical results are obtained in the blood grouping and cross-matching tests, or when reactions occur after transfusions of apparently compatible blood. Therefore, every hospital should have one or more qualified individuals responsible for the transfusions performed there. These specially qualified physicians should have the responsibility to see that the residents are properly trained to perform transfusions, and should be available to advise and assist them when problems of unusual difficulty arise. Obviously, highly technical procedures, such as an exchange transfusion, a superior longitudinal sinus transfusion, or intra-arterial transfusions, should not be undertaken except by specially trained physicians, or under the direct supervision of such individuals.

The withdrawal of blood offers fewer technical difficulties than its administration. Therefore, in many blood banks specially trained nurses or technicians are permitted to bleed donors. Wherever this is done it should be under the direct supervision of a qualified physician.

RECOMMENDATIONS

This report summarizes the present status of knowledge concerning the dangers of blood and plasma transfusion. The various untoward sequelae which may follow such transfusions and the precautions that can be taken to prevent them have been discussed in detail. It is recommended that the report be distributed to all individuals concerned with blood and plasma transfusion, in order to increase further the safety of this important therapeutic procedure.

¶ Prepared by the Bureau of Legal Medicine and Legislation, January, 1953.

ADDENDUM ¶

COURT DECISIONS

Necolayff v. Genesee Hospital, 61 N.Y.S. (2d) 832 (New York, 1946), J. A. M. A. **132**:810 (Nov. 30) 1946.—Here a hospital was sued by a patient for damages for injury which resulted because she had been given a blood transfusion in error. Patient alleged she suffered chills and a severe headache following the transfusion and later became mentally ill, spending some time in a state hospital for the insane. At the time of the transfusion patient was at or approaching her menopause and the transfusion was the turning point that caused her illness. Evidence established that a nurse and an intern, on proper order to transfuse a patient other than the plaintiff, through mistake entered plaintiff's room and commenced to administer a transfusion to her over her protest. The hospital disclaimed liability on the ground that it was a charitable hospital, although plaintiff was not a charity patient. The Supreme Court of New York, appellate division, held the hospital responsible for the negligence of its nurse and intern on the ground that the hospital, through its employees, was obligated to safeguard its patients. The nurse and intern by their negligence in entering the wrong room and transfusing the wrong patient failed to perform [illegible] administrative duty and their negligence is attributable to the hospital. Not having administered the transfusion to the proper patient the nurse's and intern's act, said the court, could not be considered a professional act.

Mississippi Baptist Hospital v. Holmes, 55 So. (2d) 142 (Mississippi, 1951), J. A. M. A. **150**:1336 (Nov. 29) 1952.—In this case a hospital was sued for the death of a patient who died as a result of having been transfused with blood of the wrong type. Evidence disclosed that a hospital laboratory technician, on proper orders, took blood samples from the deceased and another patient for the purpose of determining blood types for transfusion purposes. The types were properly ascertained by the technician as type 4 for the deceased and type 2 for the other patient, but in preparing the blood to be used for each patient the technician reversed the labels. Deceased, during surgery, was transfused with type 2 blood and death ensued as the result of acute hemolytic anemia. The hospital claimed it was not liable for its technician's negligence because it was a charitable hospital even though deceased was not a charity patient. The Supreme Court of Mississippi held the hospital liable saying that a charitable hospital should be held liable for the negligent act of its employee that proximately caused the death of the deceased to the same extent as it would had it failed to exercise reasonable care in the selection, employment, and retention of the employee. The court specifically denied that charitable hospitals enjoy immunity from liability in Mississippi solely because of their charitable character.

Parker v. State, 105 N.Y.S. (2d) 735 (New York, 1951), J. A. M. A. **148**:1359 (April 12) 1952.—Representatives of the deceased sued the state for damages resulting from death following a transfusion of pooled blood plasma infected with homologous serum jaundice. Evidence disclosed that deceased, found unattended in a critical condition, had been taken to a hospital and there, incident to shock therapy, was given a tranfusion of pooled blood plasma. Later that individual died of hepatitis, and evidence was clear that death resulted from the fact that the plasma used (war surplus blood plasma originally procured by the Red Cross for the armed forces and recently distributed to the several states through appropriate agencies) had been infected with the jaundice virus. The essence of plaintiff's action was that the state was negligent in distributing this plasma and in failing to warn of the danger of its use. The court of claims reviewed the history of blood plasma, its use, and dangers incident to its use, finding that medical experience and knowledge rendered the administration of blood or blood derivatives a recognized therapeutic device which is used in the presence of established clinical symptoms. The court also found that it is a matter of medical judgment to determine in a particular case whether to administer plasma immediately despite the danger of serum jaundice or to risk the danger of delay involved while awaiting safer whole blood properly selected or O blood treated with Witebsky's solution. The court held therefore that the state was

not negligent in distributing the plasma (a therapeutic device) or in failing to advise physicians and hospitals concerning its use (a professional decision).

National Homeopathic Hospital v. Phillips, 181 F. (2d) 293 (1950), J. A. M. A. **144:**202 (Sept. 9) 1950.—Here a hospital was sued for damages for the death of a patient following a transfusion of incompatible blood which had erroneously been tested and reported as compatible by a hospital technician. The question before the U. S. Circuit Court of Appeals was whether there was such a relationship between the hospital and the technician as to make the hospital liable for the technician's negligent act. Evidence disclosed that the hospital ordered the test to be made, that it was made by a technician hired and paid by the hospital, and that the hospital caused the transfusion to be administered in reliance on the technician's report. The test although conducted in a laboratory which was an established part of the hospital and operated under the over-all supervision of an outside physician was not made in the presence or under the supervision of the physician. The court held that a master-servant relationship did exist between the hospital and the technician and clearly established the responsibility of the hospital for the technician's negligence. The court added that this responsibility is unaffected even though a statute requires that technical work in a laboratory be put under the direction of a physician.

Brown et ux. v. Shannon West Texas Memorial Hospital, 222 S.W. (2d) 248 (Texas, 1949), J. A. M. A. **141:**1077 (Dec. 10) 1949.—Plaintiff sued the hospital and Baylor University for damages for an infection in her arm alleged to have been incurred when she donated blood in response to a request from the hospital. Plaintiff claimed the hospital was liable because it furnished a nonsterile needle to be used in withdrawing blood and the University was liable for having furnished the hospital with a contaminated needle. Evidence disclosed that under an arrangement with the University the hospital collected blood and sent it to the University for processing and return, using "collecting units" furnished by the University. These units, consisting of towels, tubing, hypodermics for local anesthesia, and needles, were sterilized and packed at the University, sent to the hospital, and there used without resterilization. While it was not disputed that plaintiff had had an infection following the procedure, her own physician testified there was no way to determine when the infection was introduced and another physician testified that the source of an infection could not be ascertained in the absence of a culture. Blood received at the University at the time in question was not contaminated. The court of civil appeals, finding that no medical expert fixed the source of the infection, said plaintiff did no more than show that her injury could have resulted from the use of a nonsterile needle. Because the plaintiff failed to prove that an infected needle was used and that the infected needle was the proximate cause of the injury judgment in favor of the hospital and University was affirmed.

Giambozi v. Peters, 16 A. (2d) 833 (Connecticut, 1940), J. A. M. A. **117:**2192 (Dec. 20) 1941.—In this case a physician was sued by representatives of a deceased patient for breach of contract to cure, for malpractice which caused a disease, and for negligence causing death. Evidence disclosed that after patient gave birth to a child her then attending physician summoned defendant to give her a transfusion. This the defendant did, using the blood of a volunteer without making a test for syphilis. Later patient having learned she had a syphilitic infection allegedly incurred as a result of the transfusion went to defendant for treatment. (He, it was alleged, agreed to effect a cure.) During treatment patient died following an injection of neoarsphenamine. The Supreme Court of Errors of Connecticut said the complaint asserted three distinct bases for recovery and held that a different statute of limitation applied to each one: for breach of contract the statute commenced at the time the contract was broken, or at death in this case; for malpractice the statute commenced when the negligent act or omission (failure to test for syphilis) occurred; and for negligence (negligence in treatment for infection) when it occurred. The court held that the action against the physician for negligence and for malpractice was barred by these statutes but that further proceedings should be held on the question of breach of contract.

MEDICAL MOTION PICTURES

Testing and Individual Therapy for Aphasic Patients: 16 mm., color, sound, showing time 28 minutes. Produced in 1950 for the Veterans Administration by Churchill-Wexler Productions, Los Angeles. Procurable on loan from VA Central Office Film Library, Motion Picture Service, Office of Information, U. S. Department of Agriculture, Washington 25.

This is the second in a series of motion pictures on aphasia. The film deals with examining procedures as well as therapy. Covering as much material as was attempted to cover in this film resulted in hitting only the high points without presenting enough detail on any one point to make the film particularly useful to students. The examination procedures demonstrated were first, neurological, second, electroencephalographic, and third, psychological, which probably results only in a small sampling of their complete testing technique. The language therapy program is very well done. There was emphasis on kinesthetic controls and training in "The Speech Act." This may be simply the result of the sampling training techniques rather than representing the particular bias on therapy.

There was an implication that certain skills were established first and contacts with other persons were second in sequence. Many therapists would reverse this order in training. The qualitative details of the film are invaluable; the stress on ideal testing conditions, the physical conditions and equipment for training, and the importance of personality and morale are all subtly presented. All in all, it is an excellent job, although some points might be controversial. The photography and narration are very well done. The film is worthy of very careful consideration by all persons who deal with aphasic patients. It would be most useful for psychologists, neurologists, and speech therapists.

Social Adjustment of the Aphasic Patient: 16 mm., color, sound, showing time 28 minutes. Produced in 1950 for the Veterans Administration by Churchill-Wexler Productions, Los Angeles. Procurable on loan from VA Central Office Film Library, Motion Picture Service, Office of Information, U. S. Department of Agriculture, Washington 25.

This is the third in a series of motion pictures on aphasia. The film shows a number of things that are important in rehabilitation work, such as group discussions of adjustment of attitudes, program in general education, occupational therapy, physical therapy, and vocational guidance. This is an excellent production. It does present a point of view for the organic basis, the examination, and training of aphasic cases. Whether or not workers in the field agree entirely with this point of view is immaterial. The most important thing is that this film represents very clearly the approach of a particular group of persons. Careful reporting of such points of view furnish a distinct contribution to scientific knowledge. The film will be of interest to psychologists and speech therapists.

NOTE: A review of the first film in this series entitled "Introduction to Aphasia" was published in THE JOURNAL, Nov. 24, 1951, page 1298.—ED.

Surgical Approaches to the Sternoclavicular and Acromioclavicular Joints: 16 mm., color, sound, showing time 19 minutes. Produced in 1952 for the Veterans Administration by Churchill-Wexler Productions, Los Angeles. Leroy C. Abbott, M.D., Technical Adviser. Procurable on loan from VA Central Office Film Library, Motion Picture Service, Office of Information, U. S. Department of Agriculture, Washington 25.

The discussion on the approaches to these two joints and the demonstration of every point of the anatomy are excellent and vivid. Having once seen the picture, one should have a clear idea as to what should be avoided and the ease with which these joints can be widely exposed. This is another product of the anatomy department of the University of California and lives up to the previous demonstrations in every way. This is a "must" for those interested in the subject illustrated. The picture is well organized, and the photography, animation, and narration are excellent. To the student, to the teacher of anatomy, and to the surgeon interested in the anatomy of the sternoclavicular and acromioclavicular joints, this film can be most heartily recommended.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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This is to certify that Sharp and Dohme Division
of Merck and Company, Incorporated *through the establishment*
identified as Sharp and Dohme Division of Merck and Company, Incorporated
located at Philadelphia, Pennsylvania *is hereby licensed, pursuant to section 351 of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), and regulations thereunder, to propagate or manufacture, and to prepare for sale in the District of Columbia, or for sending, bringing, or carrying from any State or possession into any other State or possession or into any foreign country any virus, serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound) for the propagation and manufacture of which the establishment holds an unsuspended and unrevoked license issued by the Secretary of Health, Education, and Welfare pursuant to said act and regulations.*

Date May 28, 1953

Secretary

CIVIL CRIM. 2587 EXHIBIT No. 9

UNITED STATES DISTRICT COURT

V.

STANLEY K. FORD, OFFICIAL REPORTER

202a — Exhibit No. 9

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
FEDERAL SECURITY AGENCY
WASHINGTON

E S B

MAY 28 1953

Sirs:

This Department has been advised that the name of your establishment has been changed from Sharp and Dohme, Incorporated, Philadelphia, Pennsylvania, to Sharp and Dohme Division of Merck and Company, Incorporated, Philadelphia, Pennsylvania. In view of this fact, establishment license No. 2, issued on August 4, 1944, to Sharp and Dohme, Incorporated, Philadelphia, Pennsylvania, under the provisions of the Public Health Service Act approved July 1, 1944 (58 Stat. 682), is hereby revoked without prejudice effective this date.

Upon recommendation of the Surgeon General of the Public Health Service, establishment license No. 2 is hereby reissued to Sharp and Dohme Division of Merck and Company, Incorporated, Philadelphia, Pennsylvania, effective this date. Under this license you are authorized to manufacture and sell the following products:

1. ANTITOXINS
   Tetanus Antitoxin

2. THERAPEUTIC IMMUNE SERUMS
   Antibrucella Serum
   Anti-Rocky Mountain Spotted Fever Serum
   Antitularemic Serum

3. BLOOD AND BLOOD DERIVATIVES
   Citrated Whole Blood (Human)
   Human Blood Cells
   Immune Serum Globulin (Human)
   Modified Human Globin +
   Normal Human Plasma
   Thrombin

4. BACTERIAL VACCINES
   Cholera Vaccine
   Pertussis Vaccine
   Typhoid Vaccine
   Typhoid and Paratyphoid Vaccine
   Bacterial Vaccine made from Acne Bacillus
   Bacterial Vaccine made from Brucella Abortus
   Bacterial Vaccine made from Brucella Suis
   Bacterial Vaccine made from Colon Bacillus

Bacterial Vaccine made from Dysentery Bacillus
Bacterial Vaccine made from Friedlander Bacillus
Bacterial Vaccine made from Gonococcus
Bacterial Vaccine made from Influenza Bacillus
Bacterial Vaccine made from Meningococcus
Bacterial Vaccine made from Micrococcus Catarrhalis
Bacterial Vaccine made from Pneumococcus
Bacterial Vaccine made from Pseudodiphtheria Bacillus
Bacterial Vaccine made from Staphylococcus Albus
Bacterial Vaccine made from Staphylococcus Aureus
Bacterial Vaccine made from Streptococcus
Bacterial Vaccine made from Bacterium Tularense

5. SENSITIZED BACTERIAL VACCINES

Sensitized Bacterial Vaccine made from Acne Bacillus
Sensitized Bacterial Vaccine made from Cholera Vibrio
Sensitized Bacterial Vaccine made from Colon Bacillus
Sensitized Bacterial Vaccine made from Friedlander Bacillus
Sensitized Bacterial Vaccine made from Gonococcus
Sensitized Bacterial Vaccine made from Influenza Bacillus
Sensitized Bacterial Vaccine made from Meningococcus
Sensitized Bacterial Vaccine made from Micrococcus Catarrhalis
Sensitized Bacterial Vaccine made from Paratyphoid Bacillus A
Sensitized Bacterial Vaccine made from Paratyphoid Bacillus B
Sensitized Bacterial Vaccine made from Pertussis Bacillus
Sensitized Bacterial Vaccine made from Pneumococcus
Sensitized Bacterial Vaccine made from Pseudodiphtheria Bacillus
Sensitized Bacterial Vaccine made from Staphylococcus Albus
Sensitized Bacterial Vaccine made from Staphylococcus Aureus
Sensitized Bacterial Vaccine made from Typhoid Bacillus

6. BACTERIAL ANTIGENS

Bacterial Antigen with Antihistaminic
Bacterial Antigen made from Brucella Abortus
Bacterial Antigen made from Brucella Melitensis
Bacterial Antigen made from Brucella Suis
Bacterial Antigen made from Friedlander Bacillus
Bacterial Antigen made from Influenza Bacillus
Bacterial Antigen made from Micrococcus Catarrhalis
Bacterial Antigen made from Pertussis Bacillus
Bacterial Antigen made from Pneumococcus
Bacterial Antigen made from Staphylococcus Aureus
Bacterial Antigen made from Streptococci

7. TOXOIDS AND TOXINS FOR IMMUNIZATION

Diphtheria Toxoid
Diphtheria Toxoid Protamine Precipitated
Staphylococcus Toxoid
Tetanus Toxoid

8. MULTIPLE ANTIGENS
Diphtheria Toxoid and Pertussis Vaccine Combined Alum Precipitated
Diphtheria and Tetanus Toxoids Combined Alum Precipitated
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Combined
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Combined Alum Precipitated

9. VIRAL AND RICKETTSIAL VACCINES
Influenza Virus Vaccine
Rabies Vaccine (Killed Virus)
Rocky Mountain Spotted Fever Vaccine
Smallpox Vaccine
Typhus Vaccine

10. DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS
Diphtheria Toxin for Schick Test
Scarlet Fever Streptococcus Toxin for the Dick Test
Schick Test Control
Tuberculin - Purified Protein Derivative

11. DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS
Anti-A Blood Grouping Serum
Anti-B Blood Grouping Serum

12. ALLERGENIC EXTRACTS
Poison Ivy Extract
Poison Oak Extract

13. MISCELLANEOUS
Antivenin (Latrodectus mactans)
Blood Group Specific Substances A and B
Bee Venom

Ordinarily there would be transmitted to you with this letter the license form prescribed in Section 22.4 of the Regulations (Miscellaneous Publication No. 10 approved January 16, 1947). In view of the recent change of status of this agency from the Federal Security Agency to the Department of Health, Education, and Welfare, it has been necessary to revise the license forms. As soon as these forms are available your new license will be issued as of the date of this letter. In the mean time you may accept this letter as evidence that establishment license No. 2 has been reissued to Sharp and Dohme Division of Merck and Company, Incorporated, Philadelphia, Pennsylvania, effective this date.

Sincerely yours,

Secretary

Sharp and Dohme Division of Merck and Co., Inc.
Philadelphia, Pennsylvania

STIPULATION

It is stipulated between the parties that the attached photostatisc copy of License issued to Sharp and Dohme Division of Merck and Company, Inc. for the manufacture of virus, therapeutic serum, toxin, antitoxin, or analogous products or arsphenamine or its derivatives (or any other trivalent organic arsenic compound) by the Department of Health, Education, and Welfare of the United States is a true and correct copy of the original of which it purports to be and that the same may be introduced in evidence in this cause, subject only to the objections for competency, relevancy and materiality.

(Signed) BEN F. McAULEY
Attorney for Plaintiff

(Signed) JOSEPH A. McAFEE
Attorney for Defendant

FEDERAL SECURITY AGENCY
PUBLIC HEALTH SERVICE
National Institutes of Health
Bethesda 14, Maryland
9th Revision, May 15, 1952

MINIMUM REQUIREMENTS: Normal Human Plasma

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CIVIL
CRIM. 2587 EXHIBIT NO. 10

UNITED STATES DISTRICT COURT

V.

STANLEY K. FORD, OFFICIAL REPORTER

1. THE PRODUCT

1.1 *Proper name.* - The proper name of this product is Normal Human Plasma.

1.2 *Source.* - Determination of the suitability of the donor shall be made under the supervision of a qualified doctor of medicine. Only those persons may serve as a source of Normal Human Plasma who are in physical condition to give blood, whose temperature is normal and whose blood pressure is such that blood donation will not be harmful to the donor. Donors shall be free of disease transmissible by transfusion of plasma, as far as can be determined from the personal history and from such physical examination and clinical tests as appear necessary for each donor on the day the blood is obtained. Serological tests for syphilis need not be done if the blood is to be used only for the preparation of Normal Human Plasma. As an added precaution, a history of viral hepatitis shall be cause for rejecting the donor. Existing pregnancy or pregnancy within the preceding six months shall disqualify a donor.

1.21 Only persons having not less than 12.5 gm. of hemoglobin per 100 ml. of blood shall serve as donors. Hemoglobin must be determined by a method no less accurate than the copper sulfate specific gravity method. If the copper sulfate method is used to determine hemoglobin, a specific gravity of not less than 1.053 shall be used as indicating an adequate hemoglobin level.*

1.22 Blood may be supplied by a licensed establishment to another licensed establishment for processing. Blood so supplied shall be identified adequately as to the donor, date of bleeding, and name and license number of the bleeding establishment.

1.23 Pooled plasma salvaged from ACD blood may be supplied by a licensed establishment to another licensed establishment for processing to plasma. Such pools of plasma shall be identified adequately as to donors, dates of bleeding and the name and license number of the bleeding establishment.

2. COLLECTION OF THE BLOOD FOR PLASMA

2.1 *The bleeding clinic.* - Drawing blood from the donor shall be done under the supervision of a qualified doctor of medicine with the assistance of the necessary trained attendants. The drawing may be performed in a suitable bleeding room located in the licensed laboratory, or some other place having suitable space and equipment. Irrespective of the place of bleeding, the personnel, the space and the equipment must be the responsibility of the establishment under whose license the blood is drawn.

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* – Measurements of Specific Gravity of Whole Blood and Plasma by Copper Sulphate Solutions. Robert A. Phillips, Donald D. Van Slyke, Paul V. Hamilton, Vince P. Dole, Kendall Emerson, Jr., and Reginald M. Archibald. J.B.C. *183* No. 1, 305-360: 1950.

2.2 *The anticoagulant solution.* - If the blood is collected primarily for plasma, the anticoagulant solution shall have the following composition:

Tri-sodium citrate ($Na_3C_6H_5O_7$) $2H_2O$	4.00 gm.
Water for injection (U.S.P.) to make	100 ml.

A volume of 10 ml. of this solution, for each 100 ml. of blood to be drawn, is added to the bleeding bottle before sterilization. Such bleeding bottles and donor sets used with them shall be identified by lot number and shall have been shown to be pyrogen free and sterile.

2.21 If the blood is collected for use as whole blood, or for the preparation of resuspended (or packed) red cells and plasma, one of the acid-citrate-dextrose (ACD) anticoagulant solutions described in the Minimum Requirements for Citrated Whole Blood (Human) must be used.

2.3 *Donor identification.* - A system which carries through from donor to plasma pool must be used to identify the blood. This can be accomplished best by using a suitable label or tie tag filled out for the donor at the time of completing the donor's history card. The label and history card should carry the same identification. This label or tie tag accompanies the donor to the bleeding room and is applied to the bleeding bottle while it is still possible to check accurately the identity of the blood with the donor and the history card.

2.4 *Protection of donor.* - The preparation of the skin at the site of blood collection and of injections incidental to blood collection shall be adequate to protect the donor against infection. Apparatus or instruments such as lancets, needles, syringes or other blood letting devices capable of transmitting infection from one person to another shall be heat sterilized prior to use for each donor. Heat sterilization shall be by autoclaving for 30 minutes at 121.5°C. (15 lb. pressure), by dry heat for 2 hours at 170°C., or by boiling in water for 30 minutes. (See Memorandum of Details, 3rd Revision, June 15, 1945, Section 2.)

2.5 *Method of bleeding the donor.* - The method employed for the removal of blood from the donor must conform to accepted standards of asepsis. The bleeding shall be made into a sterile system which may be either closed or vented, if adequately protected against contamination. During the bleeding the anticoagulant and the entering blood should be quickly and thoroughly mixed. Each bleeding shall be drawn into its own receiving bottle, which shall be the same container used later for centrifuging the individual bleeding. The outside of the bottle of blood must be kept clean and free of blood to protect workers against the possibility of exposure to diseases transmissible by blood.

2.6 *Storage of blood for plasma.* - Immediately after bleeding the blood shall be placed in a clean storage container at 4° to 10°C. Freezing must be avoided at all times. If transportation of the blood from the bleeding clinic to processing laboratory is necessary, it shall be transported in clean shipping cases provided with refrigeration sufficient to hold the blood at 4° to 10°C. if it has already been cooled, or sufficient to

continue the reduction of the temperature toward the 4° to 10°C. level while in transit. Immediately upon receipt at the processing laboratory it shall be placed in storage at 2° to 10°C.

3. *PREPARATION OF THE PLASMA POOL*

3.1 *The number of donors per pool.* - The supernatant plasma shall be drawn from the bleeding bottle after adequate centrifugation or sedimentation. The plasma pool shall contain individual plasmas from not less than 6 donors. No portion of a pool of plasma (for example the remainder of a test sample) may be added to another pool. The identifying numbers of all bloods contributing to a plasma pool shall be a part of the permanent records of the lot of plasma.

3.2 *Separation of the plasma.* - The blood may be removed from the refrigerator during the interval required for centrifuging and pooling. Whole blood may not be pooled before the plasma is separated from the cells. Heating of the blood during centrifugation or sedimentation should be prevented so far as possible by cooling the centrifuge or by operating the centrifuge in a room at 4° to 10°C. Following centrifugation and separation from the cells, the plasma must be distributed into the final containers, and shell frozen without needless delay. When processing liquid plasma it may be stored at 15° to 30°C. (sec. 9.4) immediately after separation.

3.21 If the whole blood has been drawn into sodium citrate anticoagulant solution, the blood shall be centrifuged within 3 days and the plasma separated from the cells within 4 days of the day the blood is drawn from the donor.

3.22 If an ACD solution has been used as the anticoagulant, the plasma may be separated from the cells for the preparation of dried or liquid plasma at any time not later than 5 days after the expiration date of the whole blood, provided the blood has been stored continuously at 4° to 10°C. since removal from the donor.

3.23 Plasma from an individual bleeding shall not be used for Normal Human Plasma if the hemoglobin content exceeds 25 mg. per 100 ml. as estimated by gross examination.

3.24 Plasma from an individual bleeding with less than 80% of the volume of blood required by the amount of anticoagulant in the bottle shall not be used for Normal Human Plasma.

For example: If the total volume is less than 450 ml. (consisting of 50 ml. 4% sodium citrate and less than 400 ml. blood) the blood shall not be used for the preparation of Normal Human Plasma.

3.25 Plasma from an individual bleeding that is markedly lipemic shall not be used for Normal Human Plasma unless the plasma is clarified by a centrifugal method, or by a method equally effective in removing fats

3.3 *The closed system defined.* - All transfers of plasma from one container to another shall be made in a sterile system, either closed or vented. The system must permit the transfer of material from one container to another entirely within the system without contamination. All air for replacement must first pass through a suitable bacteria-excluding filter, unless the transfer is made in a closed "sterility room" provided with mechanical or physical air-sterilizing devices of proven quality that are in operation during the transfer.

3.4 *Clarification of the plasma.* - Pooled plasma must be clarified to remove all particulate matter which may interfere with sterilization by ultraviolet light. The method of clarification used must be adequate to remove all red blood cells, and must not cause fibrin precipitation. Clarification may be accomplished by centrifugal or filtration methods.

3.5 *Sterilization by ultraviolet light.* - Pooled plasma shall be sterilized by ultraviolet light in accordance with the Minimum Requirements for Ultraviolet Irradiation for Sterilization of Biologic Products. It is recommended that ~~clarification~~ follow ~~irradiation~~ as a continuous process. When this is not practicable the sterilization by ultraviolet light should begin as soon as possible after clarification, but must be started within one hour after clarification. A filter shall be included in the feed line to the irradiator to remove any fibrin clots or other particles that may appear after clarification.

3.6 *Liquid plasma to contain dextrose.* - If the plasma is to be prepared as liquid plasma, it shall be stabilized, prior to storage at room temperature, by the addition of 50% dextrose U.S.P. to give a concentration of 5% dextrose in the final product. Dextrose shall not be added to plasma which is to be dried.

3.7 *Sterilization of apparatus.* - All apparatus or parts of apparatus coming in contact with plasma shall be sterilized prior to the processing of each lot.

4. *TESTS FOR STERILITY*

4.1 *Bacterial count on pooled plasma before sterilization.* - A total bacterial count shall be made on no less than 10 ml. withdrawn from each completed pool immediately before sterilization by ultraviolet light. A pool having an initial total bacterial count of not more than 10 bacteria per ml. is acceptable after ultraviolet irradiation if it meets the final container sterility test (sec. 4.3, 4.4, 4.5). A pool having an initial total bacterial count in excess of 10 bacteria per ml. is acceptable after irradiation if it meets both the final container sterility test and the test for pyrogens (sec. 5.4).

4.11 The bacterial count is made by culturing suitable dilutions in fluid thioglycollate medium. (See National Institutes of Health Circular: Culture Media for the Sterility Test, sec. 3.) Incubation is for not less than 7 days at 32° to 35°C., preferably 32°C.

4.2 *Culture media for the sterility test.* - The approved culture medium for the sterility test is the fluid thioglycollate medium or the broth medium described in detail in the National Institutes of Health circular: Culture Media for the Sterility Test. Because of the viscosity of the fluid thioglycollate medium it is essential that the inoculum be thoroughly mixed into the medium. The relative volumes of inoculum and medium and the ratio of exposed surface to volume of medium described in sec. 6 of the circular shall be maintained.

4.3 *Sterility test on the final container of liquid plasma.* - In addition to the cultural sterility test (sec. 4.32), liquid plasma shall be inspected visually for evidence of contamination at 4 and 8 weeks after filling into the final container.

4.31 After storage at 15° to 30°C. for a period of at least 4 weeks, each final container of liquid plasma shall be inspected with transmitted light. All containers showing evidence of possible contamination, such as unusual cloudiness or sediment, shall be discarded or tested for sterility. After storage at 15° to 30°C. for at least eight weeks after filling, the visual inspection and testing of possibly contaminated containers shall be repeated. If the total number of containers discarded for suspected or proven contamination exceeds 5%, the lot is unsatisfactory for distribution.

4.32 Not less than 10 ml. per liter of plasma from pools up to 50 liters total volume shall be cultured for sterility. For each liter over 50 liters in the pool, an additional 5 ml. of plasma per liter shall be cultured for sterility. The plasma shall be from a container selected at random after the first inspection and shall be cultured in one or more containers of culture medium with incubation at 32° to 35°C. (preferably 32°C.) for not less than 7 days. If contamination appears, the test may be repeated as a check on technique. The entire lot shall be discarded or reprocessed if the lot is contaminated. A reprocessed lot must pass the sterility and inspection test and the pyrogen test. (sec. 5.4.)

4.4 *Sterility test on the final container of frozen plasma.* - For this test a final container shall be selected at random from the final containers frozen as directed in sec. 8.3 and stored as directed in sec. 9.41. The container for the sterility test is then thawed as directed in sec. 9.22.

4.41 The volume of the test sample and the performance of the sterility test is the same as for liquid plasma (sec. 4.32).

4.5 *Sterility test on the final container of dried plasma.* - Not less than 5 ml. per liter of plasma from pools up to 50 liters total volume shall be cultured for sterility. For each liter over 50 liters in the pool, an additional 2.5 ml. of plasma shall be cultured. The sample may be from a random final container of dried plasma or may be a test sample filled into a final container selected at random from the containers used for the rest of the lot and shall be subjected to shell freezing, drying and stoppering under operating conditions similar to those used in processing the rest of the lot.

4.51 The performance of the sterility test is the same as for liquid plasma (sec. 4.32).

5. *OTHER TESTS*

5.1 *Potency test.* - Normal Human Plasma does not lend itself to a potency test. However, the total protein of pooled plasma should fall within the total protein range of plasma obtained from normal adult blood, after adjustment has been made for the volume of anticoagulant solution or other diluent present.

5.2 *Identity test.* - A specific identity test need not be performed if collection and processing of human plasma is conducted in laboratory space set aside for that purpose so that the accidental introduction of plasma or serum of lower animals is an impossibility.

5.3 *Safety test.* - The required sterility tests and, when indicated, a pyrogen test, constitute satisfactory safety tests.

5.4 *Pyrogen test.* - A pyrogen test, if required by sec. 4.1 or sec. 4.32, is made on final container material. This test is performed as described in Appendix A.

5.41 A pyrogen test is required on plasma distributed as liquid plasma if prepared from blood held more than 4 days before separation of the plasma from the cells and if the bacterial count or a sterility test on the pool shows evidence of contamination at any time before irradiation. The sample for this test shall be taken from the final container selected for the sterility test or from another final container selected at random at the time of the sterility test.

5.5 *Hemoglobin content.* - The completed pooled plasma shall contain not more than 25 mg. of hemoglobin per 100 ml. as determined by the method described in Appendix B.

5.6 *Moisture content of dried plasma.* - The final dried product shall not contain more than 1.00 percent of moisture and the container shall be sealed in a manner that will prevent an increase of the moisture content at any time during the dating period (sec. 9.3). "Moisture" is defined as that weight which is lost when the dried plasma is exposed over P_2O_5 in a vacuum chamber. (See Appendix C for the method of determining moisture.)

5.7 *Solubility of dried plasma.* - The reconstitution of dried plasma to a condition suitable for administration shall not require more than 3 minutes after the addition of the diluent by the method recommended in the instructions with the package.

6. *THE FINAL CONTAINER*

6.1 *Type to be used.* The final container shall be of U.S.P. Type I, II or IV glass, constructed to withstand all ordinary handling and shipping hazards without danger of breaking or otherwise impairing the product. After

filling, the container shall be closed with an air, moisture and bacteria impermeable seal and shall be equipped so that the necessary connections for the injection of the plasma into the recipient may be attached easily, directly and aseptically to the closure of the plasma container.

6.2 *Method of filling.* - The final containers are filled through a system as defined in sec. 3.3. It is recommended that a filter, adequate for the removal of particulate matter which is potentially dangerous in intravenous therapy, be placed in the filling system between the pool bottle and the final container. The entire pool is filled into final containers during a single filling operation.

6.21 Filling the final containers should begin promptly after completing the irradiation and without waiting for the report of the sterility test. The objective at all times should be to bring the plasma to its final state in the final containers as rapidly as good operating technique will permit.

6.3 *Method of handling plasma to be frozen.* - Plasma to be processed to the frozen state shall be frozen as soon as possible after filling by a method that will freeze all of the plasma within a period of 6 hours.

6.4 *Method of handling plasma to be dried.* - When plasma is to be processed to the dried state, shell freezing shall follow filling without needless delay. The drying is preferably begun without delay after shell freezing, but the shell-frozen plasma may be stored at a temperature continuously lower than minus 18°C., to await the outcome of the sterility test or to await a more convenient time for carrying out the drying process. Drying shall be accomplished by a method which is not deleterious to the plasma constituents and which will result in a sterile and readily soluble product. (sec. 5.7.)

7. *THE DILUENT FOR DRIED PLASMA*

7.1 *The proper name.* - The proper name for this diluent is Water for Injection, but the label shall carry the additional designation "Sterile, Pyrogen-free, containing 0.1 percent Citric Acid."

7.2 *Volume of diluent.* - Each container of dried plasma shall be accompanied by a sufficient amount of diluent to restore the dried plasma to at least the volume of the original plasma.

7.3 *The diluent.* - The diluent is 0.1 percent solution of citric acid in pyrogen-free, sterile distilled water. Each lot of diluent shall pass satisfactory tests for sterility and pyrogenicity.

7.4 *The container.* - The container for the diluent shall be U.S.P. Type I, II or IV glass. After filling, the container shall be closed with an air, moisture and bacteria impermeable seal and shall be equipped so that the necessary connections for the transfer of the diluent to the dried plasma may be attached easily, directly and aseptically.

8. ACCESSORY EQUIPMENT

8.1 Quality. - Accessory equipment such as needles, tubing and airway furnished with the final container of plasma shall be processed by identifying number and shall be sterile and pyrogen-free.

9. GENERAL REQUIREMENTS

9.1 Preservative. - No preservative is added. Reliance is placed entirely on good blood collection and processing techniques followed by prompt sterilization by ultraviolet radiation.

9.2 Labeling. - In addition to the items required by the Regulations the following must appear on the container label.

(1) The volume of pooled original plasma represented by the contents.
(2) The actual volume in the case of frozen or liquid plasma.
(3) The amount of added dextrose in the case of liquid plasma.

In addition to the above the following must appear on the outside label.

(1) The statement "No preservative added but treated with ultraviolet radiation."
(2) The warning "Do not freeze" in the case of dried plasma. (To prevent breakage of diluent bottle)
(3) A statement giving the method of defibrination, if applicable.
(4) A statement giving the anticoagulant used if other than sodium citrate solution.

The statement, "No U. S. Standard of Potency" need not appear.

9.21 The filling volume for liquid, frozen, or dried plasma shall be equal to the stated volume of original plasma represented plus the volume of anti-coagulant solution or other liquid added to the blood or to the plasma.

9.22 It is recommended that either the label or an accompanying circular indicate that (1) plasma should not be warmed before administration, (2) that a suitable filter must be placed in the lumen of the administration tube, (3) if dried plasma, full directions for dissolving and the manner of administration, and (4) if frozen plasma, full directions for melting, including the information that this is best done in a constant temperature device at a temperature not above 37°C.

9.23 It is recommended that either the label or an accompanying circular for dried plasma carry the statement "Use within 3 hours after restoration" and for frozen plasma the statement "Use within 3 hours after melting."

9.3 Dating. - The expiration date of liquid plasma is 2 years and of frozen plasma 5 years after the date of manufacture. The expiration date of dried plasma is 5 years after the date of manufacture or date of issue, provided the date of issue is not more than 1 year after the date of manufacture with storage at prevailing temperature not exceeding 37°C. (98.6°F.). The date of manufacture is the date of bleeding the donor.

9.4 *Storage.* - Liquid plasma shall be stored continuously as nearly as possible at a uniform temperature within the range 15° to 30°C.

9.41 Frozen plasma shall be stored continuously at minus 18°C. or lower.

9.42 Dried plasma may be stored at prevailing temperature not exceeding 37°C. (98.6°F.) provided freezing of the final package containing diluent is avoided.

9.5 *Requirements for release.* - Plasma may be released by the manufacturer when the necessary tests have been completed for each lot. When specifically requested, a sample, accompanied by a protocol detailing the information indicated in Appendix D, shall be submitted to the National Institutes of Health, Laboratory of Biologics Control, for test and release. The manufacturer shall not be required to keep reference samples from each lot. (See sec. 22.38(e) of the Regulations.)

APPENDIX A

Pyrogen Test for Plasma

Test animal. - Use healthy rabbits weighing 1500 gm. or more which have been maintained for at least 1 week on a uniform unrestricted diet and have not lost weight during this period. Use an accurate clinical rectal thermometer and test it to determine the time required to reach maximum temperature. Other recording devices of equal sensitivity are acceptable. Do not use animals which have been used for previous pyrogen tests unless they have had a rest period of not less than 48 hours and have not received previous injections of human blood products. If the animals have not been used for pyrogen tests during the previous two weeks, take four rectal temperature readings on each of the animals at 2-hour intervals 1 to 3 days before use. Insert the thermometer or other recording device beyond the internal sphincter, and allow it to remain a sufficient time to reach maximum temperature, as determined above, before the reading is recorded. Do not use in the test those animals with a temperature in excess of 39.8°C. House test animals in individual cages protected from disturbances likely to cause excitement. Exercise particular care to avoid exciting the animals on the day of taking the normal temperatures and on the test day. Maintain the animals in an environment of uniform temperature (±5°) for at least 48 hours prior to and during the test period. Preferably they should be in quarters maintained at constant temperature and humidity.

Conduct of test. - Perform the test in a room in which the temperature and the humidity are maintained at the same level as that of the room in which the animals are housed for the test. Withhold food from any animal used, beginning 1 hour before the first temperature reading, and permit no food until the day's record is completed. Access to water may be allowed. On the day of the test, take the normal temperature of each animal, using only those animals which show a normal temperature not below 38.9°C. and not above 39.8°C. This constitutes the temperature from which a subsequent rise following the injection of the test material is calculated. Warm the product to be tested to approximately 37°C. and inject intravenously, through an ear vein, 3 ml. per Kg. of rabbit, within

15 minutes subsequent to the normal temperature reading on the day of the test. Record the temperature at 1 hour subsequent to the injection and each hour thereafter until three recordings have been made. Syringes and needles used for these injections must have been treated to render them pyrogen-free and then immediately sterilized. The syringes and needles may be rendered pyrogen-free by heating in a muffle furnace at 250°C. for not less than 30 minutes, or by any other suitable method. Three rabbits shall be used for each test and the test shall be considered positive if two or three animals show an individual rise in temperature of 1.1°C. or more above the normal established for each of these animals. If only one animal shows a temperature rise of 1.1°C. or more, the test must be repeated using five rabbits. The test shall be considered positive if two or more of the group of five rabbits show an individual rise in temperature of 1.1°C. or more above the normal established for these animals.

Limits of test. - This procedure applies to Normal Human Plasma but is not the test for products which are tolerated in larger doses by rabbits.

APPENDIX B

A Method for the Determination of Hemoglobin in Plasma.

The procedure for the determination of hemoglobin in plasma is a modification of the Karr-Chornock method* and is performed in this laboratory as follows.

A. *Reagents:*

1. *Benzidine dihydrochloride reagent:*

Dissolve 140 mg. recrystallized benzidine dihydrochloride in approximately 200 ml. distilled water with warming. Cool, add 3.8 ml. 10% acetic acid and dilute to 500 ml. in a volumetric flask. Store in refrigerator.

2. *Hydrogen peroxide solution* (1%) - Dilute Merck 30% "Superoxol" or equivalent to a 1% solution of H_2O_2 with distilled water just prior to use.

B. *Test Procedure:*

Prepare a 1/10 dilution of each test sample with distilled water. To 4 ml. of this diluted plasma in a 20 x 150 mm. test tube add 15 ml. of cold (5°-10°C.) benzidine dihydrochloride reagent. Add 1 ml. of 1% H_2O_2 solution and mix well. Immerse tubes in an ice bath for 40-45 minutes to allow maximum development of the blue color. At the end of this time, colorimetric measurements of the blue color produced are made through a 650 mu. filter against a plasma control free of hemoglobin.

*Journ. Clinical Investigation, 7, 315, (1929).

Hemoglobin concentrations of the test plasma samples are then read from a curve showing absorption plotted against hemoglobin content. This curve is established as follows:

A sample of whole blood of known hemoglobin content as determined by an oxygen capacity method, iron determination or other accurate method, may be used as a standard reference material. A series of dilutions of this reference material (previously hemolyzed by dilution to 1/15 with distilled water) are made up covering the hemoglobin concentration range of 1.0 to 100 mg./100 ml. Each is tested in the same manner as described above for the test plasma with the exception that an amount of hemoglobin-free plasma is added to each tube sufficient to make the plasma protein concentrate equal to that of the final test.

APPENDIX C

A Method for the Determination of Residual Moisture

The amount of residual moisture remaining in a product which is labeled as dried shall contain not more than 1.00 percent moisture when determined by the following method: "Expose a 1 to 2 gram sample of the product, accurately weighed to the third decimal, evenly distributed in a weighing bottle not less than 60 mm. in diameter, in a vacuum desiccator at less than 1 mm. pressure, over fresh phosphorus pentoxide and at room temperature until the weight remains constant to the third decimal." In removing the sample to the weighing bottle, it is important to avoid unnecessary exposure of the dried product to the air, particularly if the moisture content of the atmosphere is relatively high. Samples of less weight may be used in smaller weighing bottles for the determination of moisture in products where full samples are not available.

APPENDIX D

RELEASE PROTOCOL FOR NORMAL HUMAN PLASMA, DRIED

1. Manufacturer _____ Date _____ Lot No. _____

2. POOLING DATA
   a. Date of drawing oldest blood_____
      Date of pooling_____
   b. Anticoagulant in blood_____
      _____
   c. Number of donors contributing to pool____
   d. Bacterial count before irradiation_____organisms per ml.
   e. Method of clarification preliminary to irradiation_____

3. IRRADIATION DATA, IRRADIATION CONTROLLER NOT USED
   a. Ultraviolet measurement prior to use.
      _____ *milliwatts 2537A°* / sq. cm. at____cm. by_____U.V. meter
   b. Flow rate_____ml./min.
   c. Biological control test. *A. aerogenes*/ml.
      Before irradiation_____
      A. aerogenes/ml. after irradiation_____

3' IRRADIATION DATA, IRRADIATION CONTROLLER USED
   a. Incident ultraviolet energy during plasma irradiation
      minimum_____ *milliwatts 2537A°* / sq. cm.
   b. Flow rate_____ ml. / min.
   c. Biological control test.
      A. aerogenes/ml. before irradiation_____
      A. aerogenes/ml. after irradiation_____

4. OTHER PROCESSING DATA
   a. Inspected for particulate matter before freezing_____Yes_____No.
   b. Time from pooling to frozen state_____hours.
   c. Time for drying_____hours.
   d. Moisture in this lot or desiccator load. Maximum %_____.
   e. Time for reconstitution_____less than 3 min._____Not done.
   f. Has the lot passed satisfactory test for:
      Sterility_____
      Identity_____
      Pyrogens_____
      (Attach protocol of pyrogen test, if test was made.)
   g. Hemoglobin_____mg. per 100 ml.

5. RECIPIENT SET (if included in package as marketed)
   a. Was recipient set processed by identifying number?_____Yes_____No.
   b. Have these recipient sets passed satisfactory test for:
      Sterility?_____ Pyrogens?_____

6. RECONSTITUTING SOLUTION FOR THIS LOT OF PLASMA
   Lot No.(s)_____
   Are tests satisfactory for:
   Sterility?_____ Pyrogens?_____

REMARKS

_____
Signature of responsible operator

APPENDIX D

RELEASE PROTOCOL FOR NORMAL HUMAN PLASMA, LIQUID

1. Manufacturer _____ Date _____ Lot No. _____

2. POOLING DATA
   a. Date of drawing oldest blood _____
      Date of pooling _____
   b. Anticoagulant in blood _____
   c. Number of donors contributing to pool _____
   d. Bacterial count before irradiation _____ organisms per ml.
   e. Method of clarification preliminary to irradiation _____

3. IRRADIATION DATA, IRRADIATION CONTROLLER NOT USED
   a. Ultraviolet measurement prior to use.
      _____ *milliwatts 2537A°* at _____ cm. by
      _____ sq. cm.
      _____ U. V. meter
   b. Flow rate _____ ml./min.
   c. Biological control test. *A. aerogenes*/ml.
      Before irradiation _____
      A. aerogenes/ml. after irradiation _____

3' IRRADIATION DATA, IRRADIATION CONTROLLER USED
   a. Incident ultraviolet energy during plasma irradiation
      minimum _____ *milliwatts 2537A°* / sq. cm.
   b. Flow rate _____ ml. / min.
   c. Biological control test.
      A. aerogenes/ml. before irradiation _____
      A. aerogenes/ml. after irradiation _____

4. OTHER PROCESSING DATA
   a. Filtered with bacterial filter. _____ Yes _____ No.
   b. Dextrose concentration _____
   c. Inspection for unusual sediment or clouding:
      Inspected after _____ days storage at _____ °C.
      Number of containers in lot _____
      Number discarded _____
      Discarded containers contaminated? _____ Yes _____ No _____ Not Tested
   d. Has the lot passed satisfactory test for:
      Sterility _____
      Identity _____
      Pyrogens _____
      (Attach protocol of pyrogen test, if test was made.)
   e. Hemoglobin _____ mg. per 100 ml.

5. RECIPIENT SET (if included in package as marketed)
   a. Was recipient set processed by identifying number? _____ Yes _____ No.
   b. Have these recipient sets passed satisfactory test for:
      Sterility? _____ Pyrogens? _____

REMARKS

_____
Signature of responsible operator

FEDERAL SECURITY AGENCY
PUBLIC HEALTH SERVICE
National Institutes of Health
Bethesda 14, Maryland
August 20, 1952

MINIMUM REQUIREMENTS: Normal Human Plasma, 9th Revision
(May 15, 1952)

AMENDMENT NO. 1

Section 2.2, page 2, is hereby amended to read as follows:

Source. - Determination of the suitability of the donor shall be the responsibility of a licensed physician and shall be done by him or under his supervision with the assistance of the necessary trained attendants. Only those persons may serve as a source of Normal Human Plasma who are in physical condition to give blood, whose temperature is normal and whose blood pressure is such that blood donation will not be harmful to the donor. Donors shall be free of disease transmissible by transfusion of plasma, as far as can be determined from the personal history and from such physical examination and clinical tests as appear necessary for each donor on the day the blood is obtained. Serological tests for syphilis need not be done if the blood is to be used only for the preparation of Normal Human Plasma. As an added precaution, a history of viral hepatitis shall be cause for rejecting the donor. Existing pregnancy or pregnancy within the preceding six months shall disqualify a donor.

AMENDMENT NO. 2

Section 2.1, page 2, is hereby amended to read as follows:

The bleeding clinic. - Drawing blood from the donor shall be the responsibility of a licensed physician and shall be done by him or under his supervision with the assistance of the necessary trained attendants. The drawing may be performed in a suitable bleeding room located in the licensed laboratory, or some other place having suitable space and equipment. Irrespective of the place of bleeding, the personnel, the space and the equipment must be the responsibility of the establishment under whose license the blood is drawn.

cyl 25

J. E. S.

FEDERAL SECURITY AGENCY
PUBLIC HEALTH SERVICE
National Institutes of Health
Bethesda 14, Maryland
February 3, 1953

MINIMUM REQUIREMENTS: Normal Human Plasma (9th Revision)

Amendment No. 3

Effective March 2, 1953, Section 9.2 is hereby amended by the addition, following Section 9.23, of Section 9.24 reading as follows:

Section 9.24 Either the label or circular for normal human plasma must carry a warning statement to the effect that despite careful donor selection and ultraviolet irradiation, the plasma may contain the virus of homologous serum hepatitis.

It is desired that the foregoing be put into effect as soon as practicable in advance of the effective date. However, packages now finished, or finished before the effective date may be issued without the statement required by this amendment.

Cofio
Dr McKeown
Dr Bogen
Dr Ellegood
Mr Fruhstorfer
Mr N. Cohen
Mr Rudy

JSS
2/9/53

Sent 2-9-53
E. Meister

APPENDIX TO BRIEF OF APPELLEE

In The

UNITED STATES DISTRICT COURT
For The Eastern District of Tennessee
Northern Division

Civil Action No. 2587

FLOYD E. KIDD,

vs.

MERCK & COMPANY, INC.

ORDER PURSUANT TO PRETRIAL

(Filed Sep. 19, 1955—Byron Pope, Clerk.)

It is agreed by counsel for the parties and ordered by the court that this statement will be binding at trial of the case on its merits:

NATURE OF ACTION:

This is an action for damages for injuries on both negligence and violation of the Uniform Sales Act adopted by this state; upon violation of the Tennessee Pure Food, Drug and Cosmetics Act.

On March 8, 1954, this plaintiff was admitted to St. Mary's Hospital, suffering from a leg injury and from loss of blood due to the leg injury. He was administered blood plasma by the hospital personnel. Some months after being administered this blood plasma, he developed a very serious

liver disease known as yellow jaundice, serum jaundice, serum hepatitis. The plasma that he was administered was manufactured by the defendant, sold by the defendant directly to the hospital, where it was injected into this patient. As a result of that disease, he suffered injuries, damages and losses for which he sues. He says that his liver has been permanently, painfully and seriously damaged, as well as his health generally, and has also suffered losses that go along with that condition. He says that the plasma that was manufactured by the defendant and placed on the market, contain this virus, known as serum hepatitis virus. He says that the manufacturer negligently placed that material on the market in sealed containers, under such circumstances as renders applicable the doctrine of res ipsa loquitur. He says that the manufacturer was negligent in placing that plasma on the market, knowing that it might contain that virus, and knowing that this plaintiff probably would not know anything at all about it. He says that the defendant breached an implied warranty of fitness under the Uniform Sales Act. He further charges that the defendant violated the Tennessee Food and Cosmetics Act and the Federal Drug and Cosmetic Act, in that the plasma did contain filthy and inherently dangerous substance, to-wit, serum hepatitis virus, and that as a result of those breaches, he has been injured, and for those injuries and loss he seeks damages.

THEORIES UPON WHICH DEFENDANT EXPECTS TO DEFEAT RECOVERY:

1. Defendant does not know whether their plasma was the plasma used on this particular patient.

2. Defendant says that there is no way, no scientific method or way, of determining whether or not whole blood or blood plasma contains hepatitis virus.

3. Defendant says that they were not negligent in the manufacture of the plasma.

4. Defendant says that in the administration of this plasma, that the entire operation was not under the control of the defendant and, therefore, the rule of res ipsa loquitur does not apply to this case.

Defendant contends that there is no implied warranty as contended by the plaintiff. Defendant says that it is not guilty of violating either the Tennessee Pure Drug Act, the Cosmetic Act, or the Federal Cosmetic and Drug Act, and that it did not violate the Uniform Sales Act.

Defendant further says as a defense that there is a certain calculated risk in administering a transfusion of whole blood or blood plasma, and that that calculated risk is well known to the medical profession, and that the plaintiff was chargeable with that knowledge, and that each and every time a transfusion takes place, they assume all of the risk that goes with such a transfusion, and that this calculated risk was especially called to the plaintiff's attention by printed instructions that went along with the defendant's plasma; that it is not only well known, but the actual information went along with the plasma and told about the calculated risk.

Defendant contends, finally, as a matter of law, that plaintiff has no right of action.

ISSUES:

Did the defendant breach any duties owed to the plaintiff and, if so, did plaintiff suffer injuries as a direct and proximate result of such breach of duty?

In the event of recovery, what is the amount of damages?

The parties shall have 10 days from September 19, 1955, in which to except to any part of this order.

Approved for docketing and filing:

ROBERT L. TAYLOR

Judge

On Petition for Certiorari

Filed October 3, 1947
W. H. Eagle, Clerk

MRS. MARY WHITE

v.

EAST TENNESSEE PACKING CO.

KNOX LAW

ON PETITION FOR CERTIORARI

The plaintiff in error instituted suit in the Circuit Court of Knox County for damages against the defendant in error, her action being based upon the violation of the State Pure Food and Drug Act, Chapter 120, Section 10, of the Acts of 1941. The declaration contained two counts, both statutory, and alleged in substance that on November 28, 1945, she purchased and paid for souse meat which was offered for sale as food for human consumption. Shortly after she made the purchase she ate a quantity of the meat, and by reason of the fact that it was not a fit food for human beings; "but unwholesome and dangerous, in that it was adulterated, as forbidden by Section 6580.10 of the Code," she was made ill and her system poisoned, from which she remained in the hospital for many days, etc.

The second count reiterated the foregoing averments and in addition alleged that defendant committed acts of negligence, as follows: (1) was negligent in processing the meat; that it was sold to plaintiff from other meat products that were diseased, contaminated, and decomposed, etc.; (2) that it failed to properly inspect the meat during its manu-

facture; (3) that said meat product was negligently held under unsanitary conditions whereby it became contaminated, etc., and was injurious to health; (4) the defendant carelessly and in a grossly negligent manner permitted said meat product to become spoiled and failed to properly refrigerate and preserve it.

The defendant pleaded not guilty. There is no doubt from the evidence offered by the plaintiff but that this souse meat was the cause of her illness. It contained certain germs which rendered it unfit for food. Dr. C. B. LeQuire testified, "It could be from any type of contamination. Most commonly, it is from the skin of people handling food."

It is shown that very soon after the meat was purchased (two pounds), the plaintiff took it home and ate some immediately upon her arrival. She became violently ill and was in the hospital for two weeks. Other persons who purchased and ate the same product also became ill.

The defendant bought the meat from a farmer and placed it in a refrigerated display case. The bacteria above referred to had no doubt developed at the time the purchase was made from the retailer at Alcoa, Tennessee. The defective or unwholesome condition of the meat could have been revealed only by a microscopic examination.

At the close of all the evidence the trial judge sustained the defendant's motion for a directed verdict on the ground that it was not guilty of any negligence. The trial judge based his action upon the case of Coca Cola Bottling Works v. Sullivan, 178 Tenn. 405.

It was the insistence of plaintiff's counsel that this was error because the evidence showed a clear violation of the statute which made a case of negligence per se, and the questions should have been submitted to the jury. The plaintiff moved for a new trial, which was overruled, and

an appeal was prayed and granted. The Court of Appeals reversed the trial court, holding that "the defendant violated the statute mentioned, and, therefore, was guilty of negligence per se," citing Queen v. Dayton Coal & Iron Co., 95 Tenn. 458, and other cases (see page 3 of the opinion.)

It appears that Mr. Justice McAmis filed an opinion in which he concurred with the majority in all respects "except that part which adopts the reasoning of the New York case cited, to-wit, Ryan v. Progressive Grocery Stores, 255 N. Y. 288, and holds that, under the Uniform Sales Act, liability would exist for breach of an implied warranty of fitness."

The plaintiff in error has filed her petition for certiorari complaining of the following errors: We need not refer to them specifically by number; it is only necessary to state the questions made for our consideration and determination. It is insisted the Court of Appeals erred (1) "in finding as a matter of law that the record in this cause presented a prima facie case of actionable negligence upon the part of the defendant entitling the plaintiff to go to the jury on that issue;" (2) "in applying the doctrine of negligence per se to this case and holding that a violation of the Tennessee Pure Food and Drug statute constitutes actionable negligence irrespective of the knowledge and good faith of the defendant;" (3) "in holding that the question of violation of the Pure Food and Drug statute should be submitted to the jury when there had been no administrative hearing on the same question before the Commissioner of Agriculture as provided by Section 7 of the Act;" (4) "in holding that the doctrine of implied warranty under the Uniform Sales Act applied to food sold at retail;" (5) "in holding that the doctrine of caveat venditor applies to retailers of food products in Tennes-

see:" (6) This assignment (Number 7 in the petition for certiorari) is merely argumentative of the principal error that the violation of the statute is not negligence per se.

It is contended by defendant that there is nothing to indicate "that the Legislature intended to enlarge the area of civil liability." The Act makes it a criminal offense to sell contaminated and unwholesome food and indicates, as we see it, an intention to protect consumers. The question of whether the Legislature intended to enlarge the field of civil liability does not control the issues in the instant case. We have many cases to the effect that the violation of a criminal statute may be made the basis of a civil action. Queen v. Dayton Coal & Iron Co., 95 Tenn. 458; Knoxville News Co. v. Spitzer, 152 Tenn. 615, and other cases therein cited.

We find no merit in the contention that before instituting a civil suit there must be a hearing before the Commissioner of Agriculture regarding an alleged violation of the statute. Code section 6580.7 provides that a case shall not be prosecuted criminally by the District Attorney General, where the Commissioner reports a violation of the Act, until the latter has given the accused notice and held a hearing upon the charge. Such a hearing is not required as a condition precedent to the right to bring a civil action for damage.

Responding to the contention that the Court of Appeals was in error in holding that defendant was liable under the doctrine of implied warranty as provided by the Uniform Sales Act, Code Section 7194 et seq., we think the plaintiff was entitled to go to the jury on the facts shown in the record regardless of the Uniform Sales Act. As to the applicability of the said Act, we at this time express no opinion.

The argument is advanced with much zeal that the opinion of the Court of Appeals will result in imposing upon every retailer of food products an unbearable burden: that in order to escape liability "he would have to set up in his premises a testing laboratory for the purpose of testing each and every article he offered for sale." The foregoing is merely an argument against the policy of the law. We are cited to no instance where a retailer of food has suffered any great hardship under decisions which support the Court of Appeals' opinion. Admitting that the Pure Food and Drug Act is exceedingly drastic in its requirements, it cannot be said that the business of processing and selling food products has been hindered in the least. We think the authority cited by the Court of Appeals fully sustains the holding that the violation of the statute is actionable per se, and proof that the defendant had knowledge of the contamination or impurity of the food at the time of sale is not a prerequisite to the right to recover. Riden v. Grimm Bros., 97 Tenn. 220.

It is not necessary to discuss the many cases cited by Judge Hale in the opinion. Suffice it to say that counsel for petitioner is silent as to the authority relied on, especially 36 C.J.S., Food, section 58, p. 1104, wherein it is said: "The sale of food in violation of the provisions of a pure food law is actionable per se," and 128 A.L.R. 456, 464. The Court quotes the following statement of the annotator:

> "And the cases almost without exception support the proposition that where the violation of a penal statute relating to the sale of unfit food or other commodity is relied upon to show negligence in a civil action in tort, knowledge of the unfitness or actual negligence in the sale of the commodity upon the part of the seller is not a condition to the maintenance of the

action where such knowledge or actual negligence is not an element of the criminal offense under the statute."

It is insisted the Court was in error in applying the maxim "caveat venditor" (1st let the seller beware), but we are cited to no authority other than the Sullivan case, which is not applicable. We think the seller should "beware" for otherwise the Pure Food and Drug Act would be without any force or effect. A contrary holding might be construed as relieving the seller of all responsibility as to the impurity or unwholesomeness of food offered for sale, in which event the buyer and consumer would have to eat at his own peril. The Court of Appeals properly distinguished the case of Coca Cola Co. v. Sullivan, supra, from the instant case.

Certiorari is denied.

Office of CLERK OF SUPREME COURT

For the Eastern Division of the State of Tennessee

I, W. H. EAGLE, Clerk of said Court, do hereby certify that the foregoing is a true, perfect and complete copy of the Opinion of said Court, pronounced at its September term, 1947, in the case of MRS. MARY WHITE against EAST TENNESSEE PACKING CO. as appears of record now on file in my office.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of the Court, at office in Knoxville, on this the 25th day of September, 1956.

/s/ W. H. EAGLE, Clerk

By ..... D. C.

(SEAL)

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FILED
MAY 23 1957
JOHN T. FEY, Clerk

In the

Supreme Court of the United States

October Term, 1956

FLOYD E. KIDD,

Petitioner,

vs.

MERCK & COMPANY, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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In the

SUPREME COURT OF THE UNITED STATES

October Term, 1956

No. ———

FLOYD E. KIDD,

Petitioner,

vs.

MERCK & COMPANY, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Floyd E. Kidd prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Sixth Circuit, entered in the above-entitled cause on April 6, 1957.

CITATIONS TO OPINIONS BELOW

The majority opinion of The Court of Appeals, and the dissenting opinion, printed in Appendix B hereto, infra, pp. 20-21, are reported in ..... F. 2d .....

JURISDICTION

The judgment of the Court of Appeals was entered on April 6, 1957. R., "Proceedings In the United States Court

of Appeals for the Sixth Circuit"; Appendix B, infra p. 14. The jurisdiction of this Court is invoked under 28 U. S. C., Section 1254 (1).

QUESTION PRESENTED

Whether, ascribing to words their ordinary meaning, the virus of serum hepatitis, contained in blood plasma, as a matter of law cannot be deemed a filthy substance within the intendment of the Tennessee Food, Drug and Cosmetic Act for the reason that the presence of the virus in plasma can be determined only by its effects upon the victim, and not by visual inspection under present-day microscopes.

In its broader aspects the question is whether the occasional victim of the disease of serum hepatitis, caused by the presence of the hepatitis virus in blood plasma, must bear the entire burden of the disease, or whether that burden should be shared by plasma manufacturers and ultimately by society as a whole.

STATUTES INVOLVED

The statutory provisions involved are Sections 52-103(a), 52-105(a), 52-110(a) (1) (2) (3) * * *, 52-115(a) (1) of the Tennessee Food, Drug and Cosmetic Act, Vol. 9 of Tennessee Code Annotated, formerly carried as Sections 6580.3(a), 6580.5(a), 6580.10(a) (1) (2) (3) * * *, and 6580.15 (a) (1) of the Supplement to the Code of Tennessee; and Sections 331(a), 333(a), 342(a) (1) (2) (3) * * *, and 351(a) (1) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U. S. C. They are printed in Appendix A, infra, pp. 11-13.

STATEMENT

On January 26, 1953, Floyd E. Kidd filed suit in the district court seeking a recovery in the amount of $50,000 for an illness caused by contaminated blood plasma manufactured and distributed by Merck & Company, Inc. The jurisdiction of the district court was invoked because of diversity of citizenship, the plaintiff being a citizen of Tennessee and the defendant a citizen of New Jersey. The original complaint charged common law negligence, breach of implied warranty of fitness, breach of the Tennessee Food, Drug and Cosmetic Act, and breach of the Federal Food, Drug, and Cosmetic Act. (R., 2a). Petitioner amended his complaint after answer was filed and proceeded to trial solely on the charge of a breach of the Tennessee Food, Drug and Cosmetic Act (R., 11a), it being his theory that a breach of that act (or of the Federal Act) amounted to negligence per se, and that under the doctrine of strict liability he would be entitled to recover upon a showing that the contaminated plasma was the proximate cause of his illness. The district judge entered judgment on a jury verdict in favor of petitioner (R., 160a), and overruled respondent's motion for judgment notwithstanding the verdict, or for a new trial (R., 166a).

The court below held that the district court was in error in failing to direct a verdict for the respondent, set aside the judgment, and ordered the case remanded with directions to enter a judgment for respondent. The assigned reason was that ascribing to words their ordinary meaning something which cannot be seen by a microscope, or the presence of which cannot be known except for its ultimate result is not a filthy substance within the intendment of the statute. (Appendix B, infra, p. 20).

The view expressed in the dissenting opinion was that the virus of serum hepatitis contained in plasma renders

it filthy, even though it cannot be seen by a microscope; "and I would consider this to be the case as a matter of law." (Appendix B, infra, p. 21).

REASONS FOR GRANTING THE WRIT

1. The question presented is of more than local significance for the reason that the Tennessee Food, Drug and Cosmetic Act is patterned upon the Federal Food, Drug, and Cosmetic Act. Under both acts, in identical language, a drug is deemed to be adulterated if, among other things, "* * * it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *". The identical provision appears in the acts of at least twelve other states[1], likewise patterned upon the Federal Act, with similar provisions in the acts of a majority of the remainder. At least one state[2] provides by statute that definitions adopted for enforcement of the Federal Act of 1938 "shall be adopted for the enforcement of this article." Furthermore, the majority opinion contains this statement: "Both parties to this appeal, however, agree that since the Tennessee law is patterned upon the Federal Act, resort may properly be had to federal court decisions construing the latter statute." (Appendix B, infra, p. 18).

2. The question presented is one which has not been but should be decided by this Court. It is of importance in the administration of the various food and drug acts. Under the majority opinion of the court below a shipment of plasma, which otherwise conforms but which, through use of a portion of the lot, is known to be contaminated with the virus in question (or any other virus ultra-microscopic in size) could not be seized by the appropriate au-

[1] Calif., Conn., Fla., Ind., La., Mo., Mass., N. H., N. Y., N. D., N. M., and Wash.

[2] Okla., 1941 Statutes, Title 63, Section 184.

thorities as adulterated. The problem at hand is one brought to light by recent achievements in the field of virology. While the record does not contain statistics as to the annual number of victims of the disease the Court judicially knows that the use of plasma is widespread, and that viral agents are playing a role of ever increasing importance in the catalogue of diseases affecting mankind. A decision of the question is of importance to these victims, to the drug industry, and to trial courts currently faced with the problem of construction here involved.

3. The decision of the court below is erroneous (a) in that it conflicts in principle with applicable decisions of this Court insofar as it turns on scienter; (b) in holding that the virus of serum hepatitis as a matter of law cannot be deemed a filthy substance; (c) in holding that the term filthy, as used in the drug act, excludes the concept of fitness except insofar as that concept pertains to rodent hair and the like; and (d) in holding that as applied to the facts of this case there is a substantial difference between the statutory definition of an adulterated food and that of an adulterated drug.

(a) Scienter — The principle of law announced in the majority opinion is as follows: "Ascribing to words their ordinary meaning, as exemplified by the cases cited, we agree with the appellant that a virus which cannot be seen even with the most powerful microscope, which cannot be described, and the presence of which cannot be known at all except for its ultimate result, is not a filthy substance within the intendment of the statute." Although this sentence begins with a reference to the ordinary meaning of words, the predominant thought is that a manufacturer may not be held liable for a harm caused by his product if he had neither the knowledge of its harmfulness nor the means of knowledge. In *United States* v. *Dottereich*,

320 U. S. 277, 281, 88 L. Ed. 48, 51, 64 S. Ct. 134, this Court held that legislation such as the Federal Food, Drug and Cosmetic Act "dispenses with the conventional requirement for criminal conduct — awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." In his dissenting opinion in *Morissette* v. *United States* 187 F. 2d 427, 434 (6 Cir., 1951); Judge McAllister stated that "where the emphasis of the statute is upon some social betterment, *scienter* is not an element of the offense * * *." In reversing the majority decision of the Court of Appeals in *Morissette*, 342 U. S. 246, 254, 91 L. Ed. 288, 296, 72 S. Ct. 240, this Court pointed out the distinction between the types of criminal offenses requiring *scienter* and those not requiring it, the latter being referred to as public welfare offenses. This Court further observed that many of the duties which have been heightened by increasingly numerous regulations "are sanctioned by a more strict civil liability * * *."

(b). The virus may be a filthy substance. — The word filthy; standing alone, is meaningless. As an adjective it becomes meaningful when used to denote a quality of the thing named. Whether the quality of filthiness may be ascribed to a particular substance depends largely upon the use to which it is put, the purpose for which it was designed, or the context in which it appears. But until the substance is known to exist no quality, of course, can be ascribed to it. This seems to be one of the points of the decision below, i.e., a virus which cannot be seen or known to exist ("*except for its ultimate result*"), cannot be said to be filthy. The italicized exception, however, makes it clear that the virus does have existence; and whether the knowledge was gained retrospectively and

clinically (R. 114a, 116a) rather than microscopically does not affect the validity of the knowledge, nor render the virus incapable of having qualities ascribed to it: interesting, filthy, ultra-microscopic, deleterious, and the like, depending upon the context in which it appears. A culture of the bacillus typhosus prepared for microscopic study ordinarily would not be considered a filthy substance. Added to a sandwich it would make the sandwich filthy just as surely as would the addition of rodent hair, and the sandwich should be subject to seizure not alone on the ground that it is "otherwise unfit for food," but also on the single ground that it consists in whole or in part of a filthy substance. The same should be equally true of a shipment of bottles of mineral water into which the culture somehow found its way. The microscopically detectible bacillus typhosis absorbed by live oysters during the process of growth from the liquid which they consumed in their natural functions was held to be a filthy substance, in *United States* v. *Sprague*, 208 Fed. 419 (D. C. N. Y., 1913). There the court said: "The ordinary use of 'adulteration' implies an actual addition to the original substance, through human agency. But the word as used in the section does not restrict this to addition by the hand of man, and if the adulteration of filthy, decomposed, or putrid substance has been added by nature, and is contained in the article to be shipped, it is adulterated in the eyes of the law." Again, "A substance containing bacilli liable to cause disease to such an extent as to make it dangerous for food purposes, is certainly 'filthy' under the meaning of that word as generally used, and especially since the result of investigation has shown that filth or dirtiness is dangerous through the germs which it contains, and not solely because of offense to the senses." No less so should be a shipment of infected plasma designed for introduction

into the human blood stream directly rather than through the gastro-intestinal tract. To impart to a victim of serum hepatitis the knowledge that he had received infected plasma undoubtedly would give offense to his senses just as certainly as would the knowledge in the case of infectious hepatitis that his disease came from drinking contaminated water or eating contaminated food. The virus of serum hepatitis, therefore, is a filthy substance if it is present in blood plasma, not only in the ordinary sense of the word, but especially as the word is used in the statute.

(c) Filthiness and injuriousness are not mutually exclusive terms. — While it is clear that the act does not require a food substance to be injurious to health to be filthy within the meaning of the statutory definition, *United States* v. *133 Cases of Tomato Paste*, 22 F. Supp. 515, 516 (E. D. Pa., 1938), it is equally clear that a substance which is injurious to health also may be filthy. *United States* v. *Sprague*, 208 Fed. 419 (D. C. N. Y., 1913). In the former case emphasis is placed upon the aesthetic tastes of the consuming public, while in the latter case emphasis is placed upon the danger to health. In *United States* v. *44 Cases, etc.*, 101 F. Supp. 658 (E. D. Ill., 1951), in response to the defendant's contention that an adulterating substance could not be deemed filthy unless injurious to health, it was held that the word should be given its ordinary meaning and not confined to any scientific or medical definition, citing *United States* v. *Swift & Co.*, 53 F. Supp. 1018 (M. D. Ga., 1943); in which latter case the defendant's contention does not appear. It is clear that all these cases further the legislative purpose of providing protection to the public. In the instant case the damage has been done and petitioner seeks partial recompense.

(d) There is no substantial difference between the statutory definition of an adulterated food and that of an adulterated drug under the facts of this case.

Under both the Federal and Tennessee Acts a food shall be deemed to be adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health * * *" (52-110(a) (1); 21 U.S.C.A. 341(a) (1), Appendix A, infra, p. 11). This particular provision was omitted from the definition of an adulterated drug. In its majority opinion the court below stated that this omission is in tacit recognition of the fact that many valuable drugs can or may contain substances of potential injury to health, and undoubtedly this is so. It is not reasonable, however, to attribute to the legislative bodies passing those acts an intention to exempt a drug containing a deleterious substance which is not a normal constituent thereof, and which is supposed not to be in the drug. This is the reason one of the medical witnesses referred to the virus as a filthy substance (R. 102a-103a), others agreed that the term was applicable in a lay sense (R. 94a, 119a, 128a), and still others in a retrospective sense (R. 118a, 135a).

It is stated in the majority opinion of the court below that if the virus were present in food the food would clearly be adulterated under the definitions referred to immediately above as the virus is a "deleterious substance" which may render food "injurious to health".

It should be noted that food containing the virus would be adulterated under Tennessee Code Annotated, Section 52-110(a) (3) and 21 U. S. C. A., Section 341(a) (3), Appendix A, infra, p. 11, because such food obviously would be unfit. Aside from it being adulterated as "otherwise unfit for food" it would be equally adulterated as containing a filthy substance. *United States* v. *Sprague*, 208 Fed. 419 (D. C. N. Y., 1913). The subsections just cited read: "* * * if it consists in whole or in part of a * * * filthy * * * substance, or if it is otherwise unfit

for food * * *." That the prohibition against filthy substances in food, and the prohibition against food otherwise unfit are independent bans is discussed in *United States* v. *1 ... Cases, etc.*, 212 F. 2d 567 (2 Cir., 1954). If the clause "otherwise unfit for food" should be disregarded, it will be seen that the remainder of the definition of an adulterated food under the sub-section cited is identical with the definition of an adulterated drug as defined in Tennessee Code Annotated, Section 52-115 (a) (1) and in 21 U. S. C. A., Section 351 (a) (1). As was noted in *Salamonie Packing Co.* v. *United States*, 165 F. 2d 205 (8 Cir., 1948), cert. den. 333 U. S. 863, "Apparently, for years, food processors have been endeavoring, unsuccessfully, to secure a ruling which would compel the Government, in cases such as this, to prove that an accused article of food contained so much decomposed matter as to make it unfit for human consumption." To the extent that the decision below holds food containing the virus to be adulterated because "injurious to health" and, inferentially, not because it contains a filthy substance, it conflicts in principle with *Salamonie*, supra, and offers encouragement to those who would have the two clauses of the acts under consideration construed as dependent rather than independent clauses.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

BEN F. McAULEY,
Counsel for Petitioner.

May 22, 1957.

APPENDIX A

STATUTES INVOLVED

Tennessee Code Annotated

"52-103. Prohibited acts. — The following acts and the causing thereof within the state of Tennessee are prohibited:

(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded. * * *

* * *

"52-105. Violations a misdemeanor — Penalty — Exceptions. — (a) Any person who violates any of the provisions of Section 52-103 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than thirty (30) days or a fine of not more than fifty dollars ($50.00), or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than six (6) months, or a fine of not more than one thousand dollars ($1,000.00), or both such imprisonment and fine. * * *

* * *

"52-110. Food deemed adulterated. — A food shall be deemed to be adulterated:

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains

any added poisonous or added deleterious substance which is unsafe within the meaning of Section 52-114; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; * * *.

* * *

"52-115. Drugs or devices deemed adulterated. — A drug or device shall be deemed to be adulterated:

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *."

21 U. S. C. A.

"Section 331. Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. * * *.

* * *

"Section 333. Penalties — Violation of section 331

(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. * * *.

* * *

"Section 342. Adulterated food

A food shall be deemed to be adulterated—

Poisonous, insanitary, etc., ingredients

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity, which is unsafe within the meaning of section 346 of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; * * *.

* * *

"Section 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

Poisonous, insanitary, etc., ingredients

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; * * *."

APPENDIX B

CAUSE ARGUED AND SUBMITTED

February 13, 1957 — Before McAllister, Miller and Stewart, Circuit Judges.

This cause is argued by Hayward H. Coburn for appellant and by Ben F. McAuley for appellee and is submitted to the court.

JUDGMENT

(Filed April 6, 1957.)

Appeal from the United States District Court for the Eastern District of Tennessee.

This cause came on to be heard on the transcript of the record from the United States District Court for the Eastern District of Tennessee, and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be and the same is hereby set aside, and the case is remanded to the District Court with directions to enter a judgment for the appellant.

OPINION

(Filed April 6, 1957.)

UNITED STATES COURT OF APPEALS
For the Sixth Circuit

No. 12918

MERCK & COMPANY, INC.,
Appellant,

vs.

FLOYD E. KIDD,
Appellee.

Appeal from the United States District Court for the Eastern District of Tennessee, Northern Division

(Decided April 6, 1957.)

Before McAllister, Miller and Stewart, Circuit Judges.

STEWART, Circuit Judge. This is an appeal from a judgment entered upon a jury verdict for personal in-

juries in a diversity of citizenship case." The underlying facts are no longer in dispute.

The appellee was injured when his leg came in contact with a power saw. His injuries were severe, consisting of a large cut in his right thigh extending down to the bone. He was taken in a state of shock to a hospital in Knoxville, where his wife signed on his behalf a consent to any medical or surgical procedure the surgeon or physician in charge of his case might deem necessary. Because of the appellee's condition the hospital's resident surgeon administered a quantity of blood plasma before performing emergency surgery. The plasma had been manufactured by the appellant.

The appellee made a normal recovery and was discharged from the hospital about a week later. Some two months thereafter, he became afflicted with jaundice, and his condition was diagnosed as probably homologous serum hepatitis. He was confined to a hospital for several days and to his home during a long period of convalescence. The jury determined that this illness had been caused by the blood plasma administered to him upon the occasion of his leg injury, and the appellant does not now dispute that finding.

The plasma in question is a dried powder which by the addition of sterile water is quickly reconstituted into liquid blood plasma which can then be administered as a substitute for whole blood. It has marked advantages over whole blood, particularly for emergency use. Among these advantages are its stability, and the fact that it can be administered safely without first determining the blood type of the recipient.

The manufacture of blood plasma is regulated by the United States Department of Health, Education and Welfare under the Virus, Serum and Toxin Act, 42 U.S.C.A.,

§ 262. The appellant was licensed under that statute to manufacture the plasma in question, and it was manufactured in conformity with the administrative standards promulgated thereunder.

The manufacturing process involves pooling the blood from a substantial number of donors and then processing the pooled blood so as to form the dried plasma. If the blood from a single donor contains the virus of serum hepatitis, there is a risk that a patient to whom the product is later administered may develop the disease. Despite every effort to screen the donors, it is recognized that the possibility that the hepatitis virus may be present in dried plasma cannot be completely obviated. Moreover, if the virus is present, it cannot be discovered by microscopic examination or by any other test known to medical science. It cannot be removed nor destroyed by any known method which does not also destroy the utility of the plasma. As counsel for the appellee concedes, "The only known way to determine whether the virus is present in any given lot of plasma is to give the plasma to a human volunteer and await developments."

Licensed manufacturers of plasma are required by federal authorities to include in the labelling of the product a warning calling the attention of physicians to the possibility that a patient to whom the product is administered will develop serum hepatitis. Such a warning accompanied the package of plasma which was administered to the appellant. The surgeon who administered it stated that he had read that warning or a similar one, and that the possibility of a patient contracting hepatitis or jaundice from blood plasma was well known to him and to the medical profession generally. He referred to it as "a so-called calculated risk."

The appellee's original complaint contained allegations of actual negligence in the manufacture of the plasma and

of breach of implied warranty of merchantable quality and fitness for use. In the amended complaint, however, these claims were abandoned, and the appellee's cause of action was bottomed specifically and exclusively upon the theory that the appellant had violated the Tennessee Food, Drug and Cosmetic Act in selling or delivering an adulterated drug as defined by that statute, and that the violation amounted to negligence *per se*. Tenn. Code Anno., §§ 52-101 through 52-124. This case, therefore, does not involve any question of the appellant's negligence in fact. Cf. *Parker* v. *State*, 112 N. Y. Supp. (2d) 695 (App. Div. 3rd Dept., 1952). Neither does it involve a claimed breach of warranty. Cf. *Perlmutter* v. *Beth David Hospital*, 308 N. Y. 100, 123 N. E. (2d) 792 (1954); *Kenower v. Hotels Statler Co.*, 124 F. (2d) 658 (6 Cir., 1942).

The Tennessee Food, Drug and Cosmetic Act is patterned upon the Federal Food, Drug and Cosmetic Act. It prohibits, among other things, the sale or delivery within that state of any food, drug, device, or cosmetic that is "adulterated." § 52-103 (a), Tenn. Code Anno. The plasma unquestionably was a "drug" as defined by the statute. § 52-102 (d), Tenn. Code Anno. A drug is "adulterated" under the statute "if it consists in whole or in part of any filthy, putrid, or decomposed substance." § 52-115, Tenn. Code Anno.

The appellee's theory was that the plasma in question was adulterated because the virus which it contained was a filthy substance. The district court admitted the testimony of several physicians upon the question of whether the virus was "filthy." The effect of this evidence was inconclusive, except to establish that there is no medical or scientific definition of the term. The court submitted the question to the jury for determination. It is the appellant's claim that this was a question of law to be deter-

mined by the court, and that as a matter of law the hepatitis virus is not a "filthy" substance within the meaning of the statute.

There have been no adjudications by the courts of Tennessee involving the meaning of these provisions of the statute. Both parties to this appeal, however, agree that since the Tennessee law is patterned upon the Federal Act, resort may properly be had to federal court decisions construing the latter statute. The meaning of "filthy" is the subject of a number of decisions by the federal courts in cases involving food, and the courts have apparently been unanimous in holding that the term is not synonymous with "injurious to health" or "unfit for food." *Salamonie Packing Co.* v. *United States*, 165 F. (2d) 205, (8 Cir., 1948), cert. den. 333 U. S. 863; *United States* v. *1851 Cartons, etc.*, 146 F. (2d) 760 (10 Cir., 1945); see *United States* v. *449 Cases, etc.*, 212 F. (2d) 567 (2 Cir., 1954). The fact that hepatitis virus is injurious is thus clearly irrelevant to the question of whether or not it is filthy. Similarly, since filthy is not synonymous with "infected" or "diseased," the trichinosis cases arising under state food and drug laws, relied upon by the appellee, shed no light upon the question in issue. See *Troietto* v. *G. H. Hammond Co.*, 110 F. (2d) 135 (6 Cir., 1940); *Leonardi* v. *Provision Co.*, 143 O. S. 623, 56 N. E. (2d) 232 (1944).

In this connection, the substantial difference between the statutory definition of an adulterated food and that of an adulterated drug is worth pointing out. If the hepatitis virus were present in food, the food would clearly be adulterated under the Tennessee statute. The virus is "a deleterious substance" which may render food "injurious to health." Tenn. Code Anno., § 52-110 (a) (1). The omission of a like provision in the statutory definition of an adulterated drug was obviously not mere inadvertence.

Tenn. Code Anno., § 52.115. The statute tacitly recognizes that many valuable drugs can or may contain substances of potential injury to health. Their use often involves the acceptance of a calculated risk by the physician who prescribes them. The physician in the present case concededly accepted just such a risk.

The federal courts have held that the word "filthy" is intended to be given its ordinary meaning. *United States* v. *Swift & Co.*, 53 F. Supp. 1018, 1020 (MD Ga., 1943); *United States* v. *44 Cases, etc.*, 101 F. Supp. 658, 664 (ED Ill., 1951). The term should not be confined to any supposed scientific or medical definition, and, by the same token, it should not be expanded beyond its accepted connotation in ordinary English speech. The substances under consideration in the cited cases were all filthy within the ordinary meaning of the word: fly eggs, maggots, and rodent hair. The federal statute has been applied to a filthy substance imperceptible to the consumer, when the substance involved was clearly filthy within the ordinary meaning of the word (worm fragments and worm excreta), and where its presence could have been prevented by proper methods of manufacture. *United States* v. *133 Cases of Tomato Paste*, 22 F. Supp. 515 (ED Pa., 1938).

The federal decision which comes closest to supporting the meaning which the appellee would ascribe to the term "filthy" is *United States* v. *Sprague*, 208 Fed. 419 (SD N. Y., 1913). That was a case decided under the Federal Pure Food and Drug Act of 1906. The court held that bacteria, particularly the *Bacillus typhosus*, which had been absorbed by live oysters, during their process of growth, rendered them filthy, "especially since the result of investigation has shown that filth or dirtiness is dangerous through the germs which it contains, and not solely because of offense to the senses." 208 Fed. 421. That decision is differenti-

able for the reason that the bacillus there involved is microscopically detectible, and, as the appellant suggests, perhaps also because the typhoid bacillus was transmitted to the oysters in human sewage and other filth.[1]

Ascribing to words their ordinary meaning, as exemplified by the cases cited, we agree with the appellant that a virus which cannot be seen even with the most powerful microscope, which cannot be described, and the presence of which cannot be known at all except for its ultimate result, is not a filthy substance within the intendment of the statute. For this reason we hold that the district court was in error in failing to direct a verdict for the appellant. This conclusion makes it unnecessary to consider the question of assumption of risk and the effect of the independent intervening act of the physician, as well as other questions raised by the appellant.

The judgment is set aside, and the case is remanded with directions to enter a judgment for the appellant.

McALLISTER, Circuit Judge, dissenting.

I regret that I am unable to concur in Judge Stewart's excellent opinion in this case.

The plasma was a drug. If it contained any filthy substance, it was adulterated, and its sale was prohibited under the Tennessee statute, as is so clearly set forth in the majority opinion. Typhoid bacilli, absorbed by live oysters, render them filthy. *United States* v. *Sprague*, 208 F. 419, cited in the majority opinion. In the similar case of clams, it is impossible to ascertain whether they are infected with typhoid bacilli, unless each clam is subjected to a bacteriological examination by microscope; and it is obviously impossible for producers or vendors to know that they are

[1] Under the present statute the oysters would be adulterated by reason of containing a "deleterious substance" rendering them "injurious to health." 21 U. S. C. A., § 342 (a) (1). See discussion above as to difference in treatment of foods and drugs in this respect.

not infected with typhoid. *Kenower* v. *Hotels Statler Co.*, 124 F. (2d) 658, 660, (C. C. A. 6).

The fact that a substance, contained in a drug, cannot be perceived by a microscope, would seem to have no bearing upon whether it is a filthy substance. Before microscopes, typhoid bacilli, absorbed by oysters, would render them filthy. In the same way, the virus of serum hepatitis contained in plasma renders it filthy, even though it cannot be seen by a microscope; and I would consider this to be the case as a matter of law. Appellee assumed no risk.

In my view, the judgment should be affirmed.

Office - Supreme Court, U.S.
FILED
JUN 20 1957
JOHN T. FEY, Clerk

IN THE

Supreme Court of the United States

October Term, 1956

No. ~~1025.~~ 135

FLOYD E. KIDD,

Petitioner,

v.

MERCK & COMPANY, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit.

BRIEF FOR RESPONDENT IN OPPOSITION.

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IN THE

Supreme Court of the United States.

October Term, 1956.

No. 1025.

FLOYD E. KIDD,

Petitioner,

v.

MERCK & COMPANY, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT.

BRIEF FOR RESPONDENT IN OPPOSITION.

OPINIONS BELOW.

The opinion of the District Court (not printed by petitioner) is unreported but may be found in the Record, p. 166a. The opinion of the Court of Appeals and the dissenting opinion (App. B of Petition) are reported at 242 F. (2d) 592.

JURISDICTION.

The jurisdictional requisites are adequately set forth in the Petition.

QUESTIONS PRESENTED.

1. Is the virus of serum hepatitis a "filthy" substance within the intendment of Section 52-115(a)(1) of the Tennessee Food, Drug and Cosmetice Act, which defines a drug as adulterated "If it consists in whole or in part of any filthy . . . substance"?

2. Where a physician, knowing that human blood plasma may contain the virus of serum hepatitis, administers such plasma to a patient in the course of his medical or surgical treatment:

(a) Does the patient's consent to treatment by the physician, even if the patient is not specifically advised of the risk of serum hepatitis, serve as a voluntary assumption of such risk which constitutes a defense to an action based on negligence presumed in law?

(b) Is the physician's failure specifically to advise the patient of the risk involved an independent, intervening act which destroys the causal connection between the assumed statutory negligence of the manufacturer of the plasma and the injury sustained by the patient?

STATUTE INVOLVED.

The only statute involved is the Tennessee Food, Drug and Cosmetic Act, and particularly Section 52-115(a)(1) thereof, printed in Appendix A to the Petition, p. 12.

The Federal Food, Drug and Cosmetic Act is *not* involved in this litigation.

STATEMENT.

This litigation involves an action by Floyd E. Kidd, the petitioner, against Merck & Company, Inc., the respondent, for damages for hepatitis contracted by Kidd following the administration to him by his physician of Normal Human Blood Plasma manufactured by the respondent. Federal jurisdiction is based on diversity of citizenship.

It is known that the blood of certain individuals contains the virus of a liver disease known as serum hepatitis and that the transfusion of such blood may produce serum hepatitis in the recipient (R., 132a; Exhibits Nos. 1 & 2, 57a, 58a, 169a, 170a). The presence of this virus in blood or blood plasma, as petitioner conceded, cannot be discovered by any method or test known to medical science (R., 76a, 77a, 104a), and the virus cannot be destroyed by any known method which does not also destroy the utility of the blood or plasma (R., 102a, 115a, 123a, 132a).

Since blood plasma is manufactured by a process which involves pooling the blood from a substantial number of donors, the blood from any one of whom may contain the virus of serum hepatitis, the use of pooled plasma involves a calculated risk that the patient to whom the product is administered will develop serum hepatitis. This risk is well known to the medical profession (R., 56a, 82a, 91a, 103a, 115a), was known to the physician who administered plasma to petitioner (R., 56a), and was specifically pointed out by respondent in a descriptive pamphlet accompanying the package of plasma that was administered to petitioner (R., Exhibits Nos. 1 & 2, 57a, 58a, 169a, 170a).

In view of these facts petitioner amended his original complaint (R., 2a-7a) and withdrew charges of negligence, breach of warranty, and violation of the Federal Food, Drug and Cosmetic Act. The amended complaint on which the case was tried (R., 11a-14a) charged solely a violation of the Tennessee Food, Drug and Cosmetic Act.

Petitioner obtained a jury verdict in the District Court (R., 160a). Respondent's motion for judgment notwithstanding the verdict (R., 161a), on the grounds (a) that the plasma was not adulterated within the meaning of the Tennessee Act, (b) that the petitioner had assumed the known risk, and (c) that the act of petitioner's physician in administering the plasma, knowing of the risk, was an independent, intervening cause of petitioner's injury, was denied (R., 166a).

On appeal the Court of Appeals, construing the Tennessee statute in the absence of any adjudication of the pertinent provisions by the courts of Tennessee, found that respondent's act did not involve a violation of the statute, and accordingly reversed the District Court and directed that judgment be entered for the respondent. It found it unnecessary, in view of this disposition of the case, to consider the questions of assumption of risk and the effect of the independent, intervening act of a physician, raised by the respondent both in the District Court and in the Court of Appeals.

ARGUMENT.

The issue in the present case is extremely narrow,—the construction by a Court of Appeals, sitting for that purpose in a diversity case as a court of Tennessee, of a Tennessee statute; and no strained semantics can change it to one which should be reviewed by this Court on certiorari.

No conflict with the decision of another Court of Appeals on this issue is or could be involved; no conflict between the decision below and any decision of the state courts of Tennessee is alleged; no question of federal law is involved; there is no decision on a federal question in conflict with the applicable decisions of this Court; and, of course, there was no departure by the court below from the accepted and usual course of judicial proceedings.

The Question Presented Involves Only Tennessee Law.

Petitioner urges that because the Tennessee Food, Drug and Cosmetic Act is patterned upon the Federal Food, Drug and Cosmetic Act, and because identical or similar provisions appear in the acts of various other states, the construction of the Tennessee Act becomes a question of general significance which should be decided by this Court. The argument, if accepted, would require this Court to review on certiorari every decision of a state court, or of a Court of Appeals in a diversity case, where the court below had construed a provision of any one of the some fifty-seven uniform acts prepared by the National Conference of Commissioners on Uniform State Laws which have been adopted in a plurality of jurisdictions, or of any state act based upon a Federal statute or the statutes of sister states.

In all such cases the local decision may be of value as a precedent in other jurisdictions, and in that sense, and that sense alone, may be of more than local significance. Petitioner fails to distinguish between the effect of the de-

cision below as a statement of applicable *law*, controlling upon other courts, and such effect, if any, as it may have as a precedent in other jurisdictions.

Under *Erie v. Tompkins*, 304 U. S. 64; 82 L. Ed. 188; 58 S. Ct. 817, a Federal court in a diversity case sits in effect as a court of the state and applies state law. It is bound to give effect to state law as determined by the courts of the state, and only where, as here, the courts of the state have not spoken may a Federal court presume to interpret the state statute. Even where the Federal court has interpreted a state statute, such interpretation cannot prevail against a subsequent, contrary interpretation by the state court. *Huddleston v. Dwyer*, 322 U. S. 232, 236; *Vandenbark v. Owens-Illinois Co.*, 311 U. S. 538, 543.

Accordingly, the decision of the Court of Appeals in this case, construing the Tennessee statute, operates only to determine the law of Tennessee and that only in the absence of a contrary interpretation of the Tennessee statute by a Tennessee court. The decision of this Court, if certiorari were granted, would go no further and would not control as a matter of law the decision of even a Tennessee court of first instance before which the interpretation of this Tennessee statute was raised. *Federation of Labor v. McAdory*, 325 U. S. 450, 471; *Huddleston v. Dwyer*, supra; *Vandenbark v. Owens-Illinois Co.*, supra.

The fact that the Tennessee Food, Drug and Cosmetic Act is patterned upon the Federal Food, Drug and Cosmetic Act and that the Court of Appeals in the absence of applicable Tennessee decisions had recourse to decisions of the Federal courts construing the Federal statute as an aid in its interpretation of the Tennessee statute in no way alters the case. The Court of Appeals did not purport to adjudicate a claim arising under the Federal statute. Such a claim, while present in the petitioner's original complaint in the District Court (R., 7a), was withdrawn by the amended complaint, which charged only a violation of the Tennessee statute (R., 14a, 18a). While both parties, and

the Court of Appeals, resorted to Federal decisions construing the Federal statute as an aid to the interpretation of the Tennessee statute, this cannot obscure or alter the fact that it was the Tennessee statute and not the Federal statute which was interpreted. Such use of Federal decisions does not by some alchemy convert a question of state law into a Federal question cognizable by this Court.

The question presented by the petition for certiorari may most simply be tested by inquiring whether, if the decision below were a decision of the Supreme Court of Tennessee instead of the Court of Appeals for the Sixth Circuit, this Court would grant certiorari. Under *Erie v. Tompkins*, supra, the test is the same.

There Is No Conflict With Any Decision of This Court.

Since certiorari will be granted on this ground only where a Court of Appeals has decided a *federal* question in a way in conflict with applicable decisions of this Court, the absence of a federal question in this case would itself suffice to deny review. However, there is no conflict, as petitioner would seek to have the Court believe, between the decision of the Court of Appeals and any decisions of this Court on the question of scienter.

The petitioner (pp. 5-6 of his brief) seeks to read into the decision of the Court of Appeals a holding that a manufacturer may not be held liable for harm caused by his product if he had neither the knowledge of its harmfulness nor the means of knowledge, citing that portion of the opinion which points out that an invisible virus whose presence can only be known by its ultimate result, is not, ascribing to words their ordinary meaning, a "filthy" substance. But this is no holding that under a pure food and drug act a manufacturer may not be held liable because he neither had knowledge nor the means of knowledge of the harmfulness of his product. The court below did not hold that the respondent did not violate the Act

because the virus was undiscoverable. It held that the respondent did not violate the Act because an undiscoverable, invisible virus, however injurious it might be, was not a "filthy" substance within the ordinary meaning of this term. The best evidence that the court below did not proceed on any principle of scienter is its statement, "If the hepatitis virus were present in food the food would clearly be adulterated under the Tennessee statute", since the virus is "a deleterious substance" which may render food "injurious to health" (App. B of Petition, p. 18).

Accordingly, petitioner's reference (pp. 5-6 of his Brief) to *United States v. Dottereich*, 320 U. S. 277, 281, 88 L. Ed. 48, 51, 64 S. Ct. 134, and *Morissette v. United States*, 342 U. S. 246; 96 L. Ed. 288; 72 S. Ct. 240, is without significance.

The Decision Below Is Correct: (a) In Its Construction of the Tennessee Statute, and (b) On Independent Grounds.

(a) Section 52-115(a)(1) of the Tennessee Food, Drug and Cosmetic Act provides that a drug shall be deemed to be adulterated "If it consists in whole or in part of any filthy, putrid or decomposed substance". Petitioner at the commencement of the trial in the District Court specifically disclaimed any contention that the virus of serum hepatitis is a "decomposed" or a "putrid" substance within the intendment of the Act and limited his case to the contention that this virus was a "filthy" substance (R., 19a). As the Court of Appeals noted in its opinion the Federal courts have repeatedly held that the word "filthy" as used in a pure food and drug act is intended to be given its ordinary meaning. *United States v. Swift & Co.*, 53 F. Supp. 1018, 1020 (MD Ga., 1943); *United States v. 44 Cases, etc.*, 101 F. Supp. 658, 664 (ED Ill., 1951). It seems perfectly clear that the virus of serum hepatitis would not be described as "filthy" in the ordinary sense of the word. It is tasteless, odorless, invisible even under the most

powerful microscope and indeed so far unknown that it is incapable of description. The real purpose of the prohibition against food or drugs containing a filthy substance is set forth in *United States v. 133 Cases, etc.*, 22 F. Supp. 515, 516 (E. D. Pa., 1938) as follows:

> "There can be no doubt that this section of the Act [referring to the precursor of 21 U. S. C. A. 342(a)(3)] was designed to protect the aesthetic tastes and sensibilities of the public. . . ."

Indeed were it not for the injurious character of the virus of serum hepatitis, no one would possibly contend that the virus was a filthy substance, and petitioner's entire effort in the court below and in his brief here is to equate in some manner the phrase "injurious to health" with the word "filthy". But as the Court of Appeals noted in its opinion (App. B to Petitioner's Brief, p. 18) the Federal courts have been unanimous in holding that the term "filthy" is *not* synonymous with "injurious to health" or "unfit for food". *Salamonie Packing Co. v. United States*, 165 F. (2d) 205, (8 Cir., 1948), cert. den. 333 U. S. 863; *United States v. 1851 Cartons, etc.*, 146 F. (2d) 760 (10 Cir., 1945); *United States v. 449 Cases, etc.*, 212 F. (2d) 567 (2 Cir., 1954).

The fact that the virus of serum hepatitis may be injurious is thus clearly irrelevant to the question of whether it is filthy, and a disregard of this distinction would ignore the very substantial difference between the statutory definition in the Tennessee Act of an adulterated food and that of an adulterated drug. A food is adulterated (Section 52-110(a)(1); App. A to Petitioner's Brief, p. 11) "If it bears or contains any poisonous or deleterious substance which may render it injurious to health", as well as if it consists in whole or in part of a filthy substance; while in the case of a drug the former provision is omitted, clearly by deliberation. To equate "injurious to health"

with "filthy" in the case of a drug, as petitioner urges, is to equate two distinct concepts which the Tennessee Legislature said were *not* to be equated.

(b) The Court of Appeals in view of its disposition of the case on the construction of the Tennessee statute found it unnecesary to consider the questions of assumption of risk and the effect of the independent, intervening act of a physician raised by respondent both in the District Court and the Court of Appeals. These defenses constitute independent grounds for sustaining the judgment of the Court of Appeals, even if it were in error in its construction of the Tennessee statute and that error were reviewable by this Court.

Each package of blood plasma sold by the respondent, including that used in treating the petitioner, contains a warning that its use involves a calculated risk of the patient's contracting serum hepatitis (R., Exhibits 1 & 2, 57a, 58a, 169a, 170a), and petitioner's attending physician testified that he had read such warnings and that he knew "It is a so-called calculated risk" (R., 56a, 60a). When the petitioner entered the hospital his wife signed on his behalf a consent to any medical or surgical procedure his physician deemed necessary (R., Exhibit 3, 99a, 173a) and petitioner testified that his wife had authority to sign such statement and that he would have approved and did approve of her having signed it (R., 34a, 35a).

Petitioner thus authorized his physician to accept the calculated risk involved in administering plasma. Since the physician accepted this risk on petitioner's behalf and was fully conscious of the existence of the risk, there was an assumption of risk which bars the petitioner from recovering from the respondent for the very risk which he assumed. That this defense, assumption of risk, is available even where liability is predicated on an alleged violation of statute rather than on actual negligence is clear. *Prosser on Torts,* (1941 Ed. p. 392); *Restatement of Torts,*

§ 286, Comment j; *Dart v. Pure Oil Company*, 223 Minn. 526; 27 N. W. (2d) 555 (1947), *Annotation*, 171 A. L. R. 894, Supplemented 10 A. L. R. (2d) 853; *Mt. Olivet Cemetery Co. v. Thomas*, 28 Tenn. App. 264, 271; 189 S. W. (2d) 1, 4, (1944) and the cases there cited.

As shown above, petitioner through his physician assumed the calculated risk involved in being treated with blood plasma. However, if petitioner should contend that the physician was not authorized by him to accept such a risk, then he is nevertheless barred from recovering because the physician's unauthorized act would be an independent, intervening cause of petitioner's injuries.

The Tennessee courts follow the general rule with respect to independent, intervening agency or cause. See *Ford Motor Company v. Wagoner*, 183 Tenn. 392, 397; 192 S. W. (2d) 840; 164 A. L. R. 364 (1946). The Court said:

> "In Bevan on Negligence, a leading text book on this subject, recognized as a classic, the chapter dealing with 'Limits of Liability' (Volume I, Fourth ed. pp. 42, 44), and discussing legal obligation to successive vendees of a compounder of drugs, or manufacturer of articles for sale to the public, dangerous to health, or in their use otherwise, thus lays down a generally recognized limitation upon liability saying (p. 42): 'A person who *knowing the perilous character* of a compound (equally applicable, clearly, to other instrumentalities fraught with danger) which he has bought, yet hands on the compound to a third person, *destroys, by his own negligent act, the causal connection between the first person concerned and the ultimate injury sustained.*'". (Emphasis by the Court.)

Thus the decision of the physician is the crucial act involved. Either the physician made this decision in accordance with the consent and authority of the patient or the physician took an unauthorized risk which constituted

an independent, intervening cause. Accordingly, in either event, whether the physician assumed the risk for petitioner or took the risk without authority, petitioner is barred from recovery.

CONCLUSION.

For the foregoing reasons it is respectfully submitted that this petition for a writ of certiorari should be denied.

Respectfully submitted,

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